

US3212326 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:50:27

All time stamps listed in this document are displayed in GMT

US3212326

Form: Participant Creation

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

[Participant ID](#)

US3212326

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

US3212326

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
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	False
Black	False
Asian	True
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) 04 Apr 2021 18:09:32

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Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 type="radio"/>
	Amendment 3 <input checked="" 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) 04 Apr 2021 18:09:32

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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) 04 Apr 2021 18:09:32

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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) 04 Apr 2021 18:09:32

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Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Condition	LEFT THYROIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Condition	LEFT THYROID NODULE, BENIGN
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 04 Apr 2021 18:09:32

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Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Condition	PLANTAR FASCIITIS LEFT FOOT
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:36 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 15:36
Height (<i>xxx.x</i>)	61 in
Weight (<i>xxx.x</i>)	113.4 lb
BMI (<i>xxx.x</i>)	21.47154 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) 04 Apr 2021 18:09:32

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 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) 04 Apr 2021 18:09:32

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Date of assessment (*dd MMM yyyy*) 27 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*) UN UNK 2005

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: Risk of Exposure

Data signed: (b) (4) 04 Apr 2021 18:09:32

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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

SOFTWARE ENGINEER/
MANAGER

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) 04 Apr 2021 18:09:32

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PARTICIPANT GOES IN PERSON TO THEIR MAIN WORKPLACE MORE THAN 2 DAYS/WEEK. PARTICIPANT INTERACTS WITH 5 OR MORE PEOPLE IN PERSON DURING THE COURSE OF A TYPICAL WORKDAY...

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 109274

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) 04 Apr 2021 18:09:33

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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)	27 AUG 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 15:36
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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)	27 AUG 2020
Time of assessment (00:00-23:59)	17:45 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:45
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 17:11 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 17:11

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) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	16:21 (24 HR)
Collection date and time (derived)	27 AUG 2020 16:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:16	27 AUG 2020 16:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 17:56

PC Open Date & Time

27 AUG 2020 17:31

PC Close Date & Time

27 AUG 2020 20:01

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 98.1 °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	27 AUG 2020 20:58
PC Open Date & Time	27 AUG 2020 20:56
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

98.4 °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

28 AUG 2020 12:30

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

98.4 °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

29 AUG 2020 13:32

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 15:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

98.5 °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

01 SEP 2020 13:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

98.4 °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

02 SEP 2020 15:25

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 17:57

PC Open Date & Time

27 AUG 2020 17:31

PC Close Date & Time

27 AUG 2020 20:01

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

27 AUG 2020 21:00

PC Open Date & Time

27 AUG 2020 20:56

PC Close Date & Time

28 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

2

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

28 AUG 2020 12:31

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

29 AUG 2020 13:32

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

30 AUG 2020 15:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

31 AUG 2020 12:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

01 SEP 2020 13:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

02 SEP 2020 15:26

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 17:58
PC Open Date & Time	27 AUG 2020 17:31
PC Close Date & Time	27 AUG 2020 20:01

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 21:01
PC Open Date & Time	27 AUG 2020 20:56
PC Close Date & Time	28 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

49 of 2415

EAB) (1725)

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:33
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

51 of 2415

EAB) (1725)

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 15:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

53 of 2415

EAB) (1725)

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

55 of 2415

EAB) (1725)

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 13:39
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

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)

57 of 2415

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 15:26
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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)	25 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:04
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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)	25 SEP 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:56
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3212326

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 11:19 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 11:19

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

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

25 SEP 2020 10:40

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:36	25 SEP 2020 10:36
Nasopharyngeal Swab 2	No		

US3212326

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °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	25 SEP 2020 12:00
PC Open Date & Time	25 SEP 2020 11:39
PC Close Date & Time	25 SEP 2020 14:09

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 100.1 °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):

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

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

PC Time Stamp 25 SEP 2020 19:03

PC Open Date & Time 25 SEP 2020 15:04

PC Close Date & Time 26 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

101.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

26 SEP 2020 12:18

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

98.0 °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

27 SEP 2020 14:46

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 14:39

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

98.2 °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

29 SEP 2020 12:05

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

98.2 °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

30 SEP 2020 13:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

98.1 °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

01 OCT 2020 16:48

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:00

PC Open Date & Time

25 SEP 2020 11:39

PC Close Date & Time

25 SEP 2020 14:09

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

5

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

25 SEP 2020 19:05

PC Open Date & Time

25 SEP 2020 15:04

PC Close Date & Time

26 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

4

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:18

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

27 SEP 2020 14:46

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

28 SEP 2020 14:39

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

29 SEP 2020 12:05

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

30 SEP 2020 13:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

01 OCT 2020 16:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 11:39
PC Close Date & Time	25 SEP 2020 14:09

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 19:06
PC Open Date & Time	25 SEP 2020 15:04
PC Close Date & Time	26 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:19
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

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EAB) (1725)

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:47
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

97 of 2415

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:39
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

99 of 2415

EAB) (1725)

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:05
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

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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US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 13:43
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

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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US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 16:49
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3212326

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:29
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212326

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3212326

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

30 OCT 2020 12:00

US3212326

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 13:13:04

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

03 NOV 2020 10:09:59

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

10 NOV 2020 10:45:52

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 19:16:51

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 10:30:04

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 09:21:17

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 11:03:01

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 15:00:25

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 12:04:33

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 08:35:02

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 08:42:48

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:44:20

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

23 JAN 2021 09:35:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

03 FEB 2021 12:43:40

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 10:15:11
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

20 FEB 2021 08:58:50

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

03 MAR 2021 11:57:13

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

06 MAR 2021 07:29:24

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

13 MAR 2021 08:37:39

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

20 MAR 2021 08:36:54

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

30 MAR 2021 15:22:45

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

07 APR 2021 09:30:46

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 11:43:17
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:40:01

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 11:02:59

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 08:30:58

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐ Yes ☐

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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°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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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°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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 <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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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°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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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°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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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="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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 <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"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

Patient Cloud Open Date & Time	01 OCT 2022 00:01
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Patient Cloud Close Date & Time	05 OCT 2022 23:59
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US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 ☐
Yes ☐

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3212326

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:50:27

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		03 MAR 2021 11:57:24

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

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

Visit date (dd MMM yyyy)	26 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 10:15
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212326

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3212326

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	26 MAR 2021 10:45

US3212326

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 18:09:33

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 19:36:13

Generated On: 09 Jun 2021 15:50:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212326

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 19:36:13

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

Date of Contact	18 NOV 2020
Time of Contact	10:08
Date and Time of Contact (derived)	18 NOV 2020 10:08
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

Symptom Day

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

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

	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"/>

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

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

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Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

Date of Contact	20 OCT 2020
Time of Contact	15:33
Date and Time of Contact (derived)	20 OCT 2020 15:33
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

Symptom Day

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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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US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 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 type="radio"/>
	Mild	<input checked="" 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 20 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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 ☐

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 type="radio"/>
	Mild	<input checked="" 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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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	19 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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"/>

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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"/>

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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"/>

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 20 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

	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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

Date of Visit	20 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	20 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	22 OCT 2020
Day 5	NA (COVID-19 Negative)	
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)	

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 14:37
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3212326

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 OCT 2020

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID SICKD28

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:30

Generated On: 09 Jun 2021 15:50:27

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) _____

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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.

US3212326

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3212326

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

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

Visit date (dd MMM yyyy)	27 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3212326

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:36:13

Generated On: 09 Jun 2021 15:50:27

Date of updated informed consent (dd MMM yyyy) 27 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 27 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3212326

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

15:55 (24 HR)

Collection date and time (derived)

27 JAN 2021 15:55

US3212326

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 18:09:31

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	15:50
Collection Date and Time (derived)	27 JAN 2021 15:50

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Folder: Unscheduled 03 Dec 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Visit Date	03 DEC 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	09:48 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 09:48
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 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: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 10:10
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 18:09:32

Generated On: 09 Jun 2021 15:50:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 19:15:01

Generated On: 09 Jun 2021 15:50:27

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:15:00

Generated On: 09 Jun 2021 15:50:27

AEID

Adverse event

ACUTE NON-RECURRENT
PANSINUSITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 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 ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 19:15:00

Generated On: 09 Jun 2021 15:50:27

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

Data signed: (b) (4) 16 Apr 2021 19:15:00

Generated On: 09 Jun 2021 15:50:27

AEID

Adverse event

POST-NASAL DRIP

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)

25 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 DEC 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 (6)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (7)

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AEID	USA-US115-2020-MRNA-1273-P30 1000011
Adverse event	AUTONOMIC DYSFUNCTION
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)	25 SEP 2020
Start time (00:00-23:59)	17:00 (24 HR)
AE start date and time (derived)	25 SEP 2020 17:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	15:00 (24 HR)
AE End Date and Time (derived)	01 MAR 2021 15:00
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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PALPITATIONS
Narrative	

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SUBJECT REPORTED SYMPTOMS OF INTERMITTENT PALPITATIONS AND INTERMITTENT DIZZINESS STARTED IN LATE OCTOBER ABOUT 3 WEEKS AFTER THE SECOND VACCINATION. SHE IS UNABLE TO TOLERATE HER USUAL LEVEL OF ACTIVITY/EXERCISE. IN THE PAST SHE WAS ABLE TO RUN 10 MILES WITHOUT PROBLEMS. RECENTLY, SHE COULD RUN ONLY A MILE. LATELY, IF SHE WALKS A BLOCK, SHE WILL DEVELOP HEART PALPITATIONS (HEART POUNDING) AND DIZZINESS. SHE DENIES ANY SPINNING SENSATION RECENTLY. SHE REPORTS HAVING NORMAL THYROID TEST AND OTHER BLOOD WORK. NO REPORTED SYNCOPE OR DEPRESSION. SHE WAS REFERRED TO A CARDIOLOGIST AND FOR A HOLTER MONITOR, BUT SHE HASN'T DONE THESE YET. SHE FINISHED ANTIBIOTICS FOR POSSIBLE SINUS INFECTION. SHE CONTINUES TO HAVE SYMPTOMS OF FATIGUE AND DIZZINESS THAT LIMIT HER EXERCISE AND ACTIVITIES. CXR WAS NORMAL. LABS ARE

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NORMAL INCLUDING TSH, CBC,
CHEMISTRIES, AST, ALT, AND
D-DIMER. EKG WAS
NORMAL-WE DID ON SITE
(18NOV2020). SHE HAS
INTERMITTENT DIZZINESS AND
VERTIGO OFTEN PRECIPITATED
BY EXERCISE. MRI BRAIN
SHOWED NO ACUTE
CHANGES-CSF COLLECTION AT
THE R
CEREBELLOMEDULLARY
ANGLE SUGGESTIVE OF AN
ARACHNOID CYST. HALLPIKE
MANEUVER WAS NEGATIVE-
NO NYSTAGMUS (SHE WAS
BRIEFLY DIZZY) BP/PULSE
TILT: 118/79 PULSE 71 LYING;
111/77 PULSE 76 STANDING; NO
TILT; COVID SWAB DONE ON
19NOV2020 TO EVALUATE FOR
POSSIBLE LONG COVID
SYNDROME. HER SYMPTOMS
OF FATIGUE, DIZZINESS, AND
PALPITATIONS ARE POSSIBLY
RELATED TO THE STUDY
PRODUCT. THE SYMPTOMS ARE
TEMPORALLY RELATED. SHE
WAS REFERRED TO GET A
HOLTER MONITOR AND
CARDIOLOGY EVALUATION BY
HER DOCTOR. SHE WAS
THINKING OF POSTPONING
THIS DUE TO COST SINCE SHE
HAS HIGH DEDUCTIBLE

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Form: Adverse Events (7)

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INSURANCE. SHE THINKS HER
SYMPTOMS ARE RELATED TO
THE STUDY TREATMENT AND
WANTS ASSISTANCE WITH THE
COST OF THIS WORK UP. I
ENCOURAGED HER TO GET
FURTHER EVALUATION WITH
THE CARDIOLOGIST/ HOLTER
MONITORING AND POSSIBLY
NEUROLOGY.

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)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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AEID

Adverse event FATIGUE

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) 20 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐ No ☒

If not Ongoing, end date (dd MMM yyyy) 24 DEC 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 (8)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (9)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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AEID	
Adverse event	INTERMITTENT PALPITATIONS
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)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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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Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (10)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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AEID

Adverse event

FREQUENT MENSTRUATION

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)

8 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)

27 DEC 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 (10)

Data signed: (b) (4) 16 Apr 2021 19:15:00

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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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication LEVOTHYROXINE
(SYNTHROID)

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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 (1)

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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 JUN 2006	
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) 04 Apr 2021 18:07:05

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER/PAIN REACTOGENICITY

Dose per administration 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication FORMETEROL

Prophylaxis Yes ☐
No ☒

Indication AUTONOMIC DYSFUNCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 18:07:05

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication AMOXICILLIN/CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE NON-RECURRENT
PANSINUSITIS

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 ☐

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US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

	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)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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 (5)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication AUTONOMIC DYSFUNCTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

	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)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication B COMPLEX- VITAMIN C-FOLIC
ACID (FOLBEE PLUS)

Prophylaxis Yes ☒
No ☐

Indication DEFICIENCY; GENERAL
HEALTH

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication CALCIUM CARBONATE -
VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication DEFICIENCY; GENERAL
HEALTH

Dose per administration 500 / 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication LUTEIN-ZEAXANTHIN

Prophylaxis Yes ☒
No ☐

Indication EYE HEALTH; GENERAL
HEALTH

Dose per administration 25 /5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

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

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication DEFICIENCY; GENERAL HEALTH

Dose per administration 1200

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

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EAB) (1725)

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

	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 2014	
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"/>

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 Apr 2021 18:07:05

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 DEC 2020	ECHOCARDIOGRAM	Adverse Event	
16 DEC 2020	CARDIAC STRESS TEST	Adverse Event	
16 DEC 2020	HOLTER MONITOR (AMBULATORY EKG)	Adverse Event	
07 DEC 2020	CHEST X-RAY	Adverse Event	
07 DEC 2020	MRI HEAD	Adverse Event	

US3212326

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:50:27

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 ☐

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 14:53:54

Generated On: 09 Jun 2021 15:50:27

SAEID	USA-US115-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 14:53:54

Generated On: 09 Jun 2021 15:50:27

SAEID	USA-US115-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/NOV/2020 17:02
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

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 14:53:54

Generated On: 09 Jun 2021 15:50:27

SAEID	USA-US115-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 14:53:54

Generated On: 09 Jun 2021 15:50:27

SAEID	USA-US115-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 05:56
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

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 14:53:54

Generated On: 09 Jun 2021 15:50:27

SAEID	USA-US115-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 10:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3212326 (Prod: DM Clinical Research - ERN - PPDS)

US3212326

Form: Participant Creation

Generated On: 09 Jun 2021 15:50:27

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:42:17
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'US3212326'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:14:19

US3212326

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:18:53

US3212326

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:17:00
User entered '27 AUG 2020'	(b) (4), (b) (6)	27 Aug 2020 21:14:20
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

US3212326

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:17:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	
	Afifah Ayub (b) (4)	27 Aug 2020 21:18:53
	(b) (4)	

US3212326

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'SCRN'	System	27 Aug 2020 21:18:53

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:17:39
User entered (b) (6) 1974'	(b) (4), (b) (6)	27 Aug 2020 21:14:21
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '46'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'YEARS'	System	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '46'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered 'Female (F)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:50:27

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered '0'	Afifah Ayub (b) (4)	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Aug 2020'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2020'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered 'Amendment 3 (3)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:20:35
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:20:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:14:20

US3212326

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:50:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'I'	System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:53
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:50:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:25:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:14:32

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 21:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 21:16:36
Data point term sent to Coder	System	30 Aug 2020 21:15:09
User entered 'Hypothyroidism'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:26:31
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2006'	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2006'	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered empty.	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered empty.	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 21:17:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 21:17:51
Data point term sent to Coder	System	30 Aug 2020 21:16:09
User entered 'Left Thyroidectomy'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:01:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:01:46
Data point term sent to Coder	System	30 Aug 2020 21:16:09
User entered 'Left Thyroid Nodule, benign'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 21:17:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 21:17:36
Data point term sent to Coder	System	30 Aug 2020 21:16:11
User entered 'Bilateral Tubal Ligation'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2005'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'No (N)'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:26:31
User entered 'Un UNK 2005'	(b) (4), (b) (6)	
	Afifah Ayub (b) (4)	30 Aug 2020 21:15:50
	(b) (4)	

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:19
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:52:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:52:12
Data point term sent to Coder	System	25 Nov 2020 14:50:41
User entered 'Plantar Fasciitis Left Foot'	Afifah Ayub (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Un UNK 2015'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:24
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:25
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:27
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'UN UNK 2015'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:43:28
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2015'	System	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2015'	System	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'Jan 2015'	System	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '2015'	System	25 Nov 2020 14:49:43

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:44
User entered '15:36'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered '27 Aug 2020 15:36'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:49
User entered '61' in	Afifah Ayub (b) (4)	27 Aug 2020 21:19:58
DataPoint set to visible.	(b) (4) System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:51
User entered '113.4' lb	Afifah Ayub (b) (4)	27 Aug 2020 21:19:58
DataPoint set to visible.	(b) (4) System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
Amendment Manager: User entered '21.47154'	System	17 Sep 2020 00:06:11
User entered '21.5'	System	27 Aug 2020 21:19:58
DataPoint set to visible.	System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'kg/m2'	System	27 Aug 2020 21:19:58
DataPoint set to visible.	System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 19:37:21
User entered 'Other (Other)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 19:37:21
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'bpm'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'breaths/min'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'mmHg'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	16 Oct 2020 18:26:56
User entered missing code ND - Not Done.	(b) (4), (b) (6)	
	Afifah Ayub (b) (4)	27 Aug 2020 21:19:58
	(b) (4)	

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User entered 'mmHg'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09

US3212326

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:06

US3212326

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:10
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:06

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered '27 Aug 2020'	Afifah Ayub (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered 'Surgically sterile (SURGICALLY STERILE)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered 'UN UNK 2005'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:50:27

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

[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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

[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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'No (N)'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'Software Engineer/ Manager'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered '0'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered '0'	Afifah Ayub (b) (4)	27 Aug 2020 21:22:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:50:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:24:09
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:44
User entered 'Participant goes in person to their main workplace more than 2 days/week. Participant interacts with 5 or more people in person during the course of a typical workday...'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:46:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:46:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:46:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'VISIT1'	System	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:24:38

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '109274'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:24:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:24:38

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

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)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

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)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:50:27

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:47:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4)	28 Sep 2020 17:10:53
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:21:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:21:33

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:58
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:28:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:58
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:28:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:28:02
User entered '15:36'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '27 Aug 2020 15:36'	System	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '98' F	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '59'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'bpm'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '15'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'breaths/min'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '106'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '72'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:27:58
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:50:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:28:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '17:45'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '27 Aug 2020 17:45'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '97.3' F	Afifah Ayub (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	30 Aug 2020 21:18:01
	(b) (4)	

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '58'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'bpm'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '16'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'breaths/min'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '104'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '63'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:18:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:39
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:18

US3212326

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:18

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered empty.	Afifah Ayub (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered '17:11'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '27 Aug 2020 17:11'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:33:52
User entered 'ONCE'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:03
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:36

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:34:03
User entered '27 Aug 2020'	Afifah Ayub (b) (4)	27 Aug 2020 21:41:36

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:03
User entered '16:21'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:36

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '27 Aug 2020 16:21'	System	27 Aug 2020 21:41:36

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:29
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:29
User entered '16:16'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '27 Aug 2020 16:16'	System	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered empty.	System	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:34:37
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:53

US3212326

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	27 Aug 2020 21:41:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:56:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a2f00538-0a8c-4614-ae6-0874ea8d44c6'	System	27 Aug 2020 22:49:37
User entered 'Yes (Y)'	System	27 Aug 2020 22:49:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:56:38', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a2f00538-0a8c-4614-ae6-0874ea8d44c6'	System	27 Aug 2020 22:49:37
User entered '97.3'	System	27 Aug 2020 22:49:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:56:42', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a2f00538-0a8c-4614-ae6-0874ea8d44c6'	System	27 Aug 2020 22:49:37
User entered 'No (N)'	System	27 Aug 2020 22:49:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:56:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a2f00538-0a8c-4614-ae6-0874ea8d44c6'	System	27 Aug 2020 22:49:37
User entered '27 Aug 2020 17:56'	System	27 Aug 2020 22:49:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 17:31'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T20:58:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '859601c4-9ff1-4434-a836-e916293e8c1e'	System	28 Aug 2020 01:51:25
User entered 'Yes (Y)'	System	28 Aug 2020 01:51:25

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T20:58:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '859601c4-9ff1-4434-a836-e916293e8c1e'	System	28 Aug 2020 01:51:25
User entered '98.1'	System	28 Aug 2020 01:51:25

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T20:58:32', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '859601c4-9ff1-4434-a836-e916293e8c1e'	System	28 Aug 2020 01:51:25
User entered 'No (N)'	System	28 Aug 2020 01:51:25

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T20:58:38', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '859601c4-9ff1-4434-a836-e916293e8c1e'	System	28 Aug 2020 01:51:25
User entered '27 Aug 2020 20:58'	System	28 Aug 2020 01:51:25

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:56'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 2'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:29:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '317d2679-a039-431c-a85a-8ebe0b43e28d'	System	28 Aug 2020 17:22:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:22:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:29:53', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '317d2679-a039-431c-a85a-8ebe0b43e28d' User entered '98.4'	System	28 Aug 2020 17:22:53
	System	28 Aug 2020 17:22:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:29:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '317d2679-a039-431c-a85a-8ebe0b43e28d'	System	28 Aug 2020 17:22:53
User entered 'No (N)'	System	28 Aug 2020 17:22:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:30:03', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '317d2679-a039-431c-a85a-8ebe0b43e28d'	System	28 Aug 2020 17:22:53
User entered '28 Aug 2020 12:30'	System	28 Aug 2020 17:22:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 3'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f18d7fd-53c5-410c-8691-c2db2c013bfa'	System	29 Aug 2020 18:25:22
User entered 'Yes (Y)'	System	29 Aug 2020 18:25:22

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f18d7fd-53c5-410c-8691-c2db2c013bfa'	System	29 Aug 2020 18:25:22
User entered '98.4'	System	29 Aug 2020 18:25:22

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:29', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f18d7fd-53c5-410c-8691-c2db2c013bfa'	System	29 Aug 2020 18:25:22
User entered 'No (N)'	System	29 Aug 2020 18:25:22

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f18d7fd-53c5-410c-8691-c2db2c013bfa'	System	29 Aug 2020 18:25:22
User entered '29 Aug 2020 13:32'	System	29 Aug 2020 18:25:22

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 4'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '99dd9dcf-2099-4e18-b6c9-0e2b01c56ff7'	System	30 Aug 2020 19:56:07
User entered 'Yes (Y)'	System	30 Aug 2020 19:56:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '99dd9dcf-2099-4e18-b6c9-0e2b01c56ff7'	System	30 Aug 2020 19:56:07
User entered '97.9'	System	30 Aug 2020 19:56:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:13', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '99dd9dcf-2099-4e18-b6c9-0e2b01c56ff7'	System	30 Aug 2020 19:56:07
User entered 'No (N)'	System	30 Aug 2020 19:56:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '99dd9dcf-2099-4e18-b6c9-0e2b01c56ff7'	System	30 Aug 2020 19:56:07
User entered '30 Aug 2020 15:03'	System	30 Aug 2020 19:56:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 5'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '635c680d-7378-47be-8180-4b466a89936f'	System	31 Aug 2020 16:58:55
User entered 'Yes (Y)'	System	31 Aug 2020 16:58:55

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '635c680d-7378-47be-8180-4b466a89936f' User entered '98.3'	System	31 Aug 2020 16:58:55
	System	31 Aug 2020 16:58:55

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '635c680d-7378-47be-8180-4b466a89936f'	System	31 Aug 2020 16:58:55
User entered 'No (N)'	System	31 Aug 2020 16:58:55

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '635c680d-7378-47be-8180-4b466a89936f'	System	31 Aug 2020 16:58:55
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:58:55

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 6'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:01', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8c2a23f5-b1d1-4f3a-b258-c5b8df59b886'	System	01 Sep 2020 18:32:01
User entered 'Yes (Y)'	System	01 Sep 2020 18:32:01

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8c2a23f5-b1d1-4f3a-b258-c5b8df59b886'	System	01 Sep 2020 18:32:01
User entered '98.5'	System	01 Sep 2020 18:32:01

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8c2a23f5-b1d1-4f3a-b258-c5b8df59b886'	System	01 Sep 2020 18:32:01
User entered 'No (N)'	System	01 Sep 2020 18:32:01

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:15', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8c2a23f5-b1d1-4f3a-b258-c5b8df59b886'	System	01 Sep 2020 18:32:01
User entered '01 Sep 2020 13:39'	System	01 Sep 2020 18:32:01

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 7'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:35', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8eaaaada-8a80-4bcd-bc3a-bd37789a33fc'	System	02 Sep 2020 20:18:37
User entered 'Yes (Y)'	System	02 Sep 2020 20:18:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8eaaaada-8a80-4bcd-bc3a-bd37789a33fc'	System	02 Sep 2020 20:18:37
User entered '98.4'	System	02 Sep 2020 20:18:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8eaaaada-8a80-4bcd-bc3a-bd37789a33fc'	System	02 Sep 2020 20:18:37
User entered 'No (N)'	System	02 Sep 2020 20:18:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8eaaaada-8a80-4bcd-bc3a-bd37789a33fc'	System	02 Sep 2020 20:18:37
User entered '02 Sep 2020 15:25'	System	02 Sep 2020 20:18:37

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '66539fab-12c6-4e29-b83e-ae6d6a071e89'	System	27 Aug 2020 22:50:40
User entered 'None (1)'	System	27 Aug 2020 22:50:40

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:35', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '66539fab-12c6-4e29-b83e-ae6d6a071e89'	System	27 Aug 2020 22:50:40
User entered 'No (N)'	System	27 Aug 2020 22:50:40

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '66539fab-12c6-4e29-b83e-ae6d6a071e89'	System	27 Aug 2020 22:50:40
User entered 'No (N)'	System	27 Aug 2020 22:50:40

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '66539fab-12c6-4e29-b83e-ae6d6a071e89'	System	27 Aug 2020 22:50:40
User entered 'None (1)'	System	27 Aug 2020 22:50:40

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '66539fab-12c6-4e29-b83e-ae6d6a071e89'	System	27 Aug 2020 22:50:40
User entered '27 Aug 2020 17:57'	System	27 Aug 2020 22:50:40

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 17:31'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T20:58:51', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cc8c7948-760c-44a7-8621-ab4cd9b1f21e'	System	28 Aug 2020 01:53:22
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:53:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:03', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cc8c7948-760c-44a7-8621-ab4cd9b1f21e'	System	28 Aug 2020 01:53:22
User entered 'No (N)'	System	28 Aug 2020 01:53:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cc8c7948-760c-44a7-8621-ab4cd9b1f21e'	System	28 Aug 2020 01:53:22
User entered 'No (N)'	System	28 Aug 2020 01:53:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cc8c7948-760c-44a7-8621-ab4cd9b1f21e'	System	28 Aug 2020 01:53:22
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:53:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:34', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cc8c7948-760c-44a7-8621-ab4cd9b1f21e'	System	28 Aug 2020 01:53:22
User entered '27 Aug 2020 21:00'	System	28 Aug 2020 01:53:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:56'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 2'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:30:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:30:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered 'No (N)'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:30:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered 'Yes (Y)'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:30:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered '2'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered 'None (1)'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '89d8bbbb-1ad8-48b7-9a6b-24af74cc289d'	System	28 Aug 2020 17:23:54
User entered '28 Aug 2020 12:31'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 3'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:42', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '398698b4-11c7-47c7-a5eb-fe4b6a372541'	System	29 Aug 2020 18:25:42
User entered 'None (1)'	System	29 Aug 2020 18:25:42

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '398698b4-11c7-47c7-a5eb-fe4b6a372541'	System	29 Aug 2020 18:25:42
User entered 'No (N)'	System	29 Aug 2020 18:25:42

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '398698b4-11c7-47c7-a5eb-fe4b6a372541'	System	29 Aug 2020 18:25:42
User entered 'No (N)'	System	29 Aug 2020 18:25:42

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:51', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '398698b4-11c7-47c7-a5eb-fe4b6a372541'	System	29 Aug 2020 18:25:42
User entered 'None (1)'	System	29 Aug 2020 18:25:42

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:32:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '398698b4-11c7-47c7-a5eb-fe4b6a372541'	System	29 Aug 2020 18:25:42
User entered '29 Aug 2020 13:32'	System	29 Aug 2020 18:25:42

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 4'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '553c8f49-c954-4ffb-b07b-847fbc88e3c1'	System	30 Aug 2020 19:56:19
User entered 'None (1)'	System	30 Aug 2020 19:56:19

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '553c8f49-c954-4ffb-b07b-847fbc88e3c1'	System	30 Aug 2020 19:56:19
User entered 'No (N)'	System	30 Aug 2020 19:56:19

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:27', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '553c8f49-c954-4ffb-b07b-847fbc88e3c1'	System	30 Aug 2020 19:56:19
User entered 'No (N)'	System	30 Aug 2020 19:56:19

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:30', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '553c8f49-c954-4ffb-b07b-847fbc88e3c1'	System	30 Aug 2020 19:56:19
User entered 'None (1)'	System	30 Aug 2020 19:56:19

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '553c8f49-c954-4ffb-b07b-847fbc88e3c1'	System	30 Aug 2020 19:56:19
User entered '30 Aug 2020 15:03'	System	30 Aug 2020 19:56:19

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 5'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3057ac67-3552-4295-908e-dd21485086f6'	System	31 Aug 2020 16:59:00
User entered 'None (1)'	System	31 Aug 2020 16:59:00

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3057ac67-3552-4295-908e-dd21485086f6'	System	31 Aug 2020 16:59:00
User entered 'No (N)'	System	31 Aug 2020 16:59:00

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3057ac67-3552-4295-908e-dd21485086f6'	System	31 Aug 2020 16:59:00
User entered 'No (N)'	System	31 Aug 2020 16:59:00

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3057ac67-3552-4295-908e-dd21485086f6'	System	31 Aug 2020 16:59:00
User entered 'None (1)'	System	31 Aug 2020 16:59:00

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3057ac67-3552-4295-908e-dd21485086f6'	System	31 Aug 2020 16:59:00
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:59:00

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 6'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'b4501e5b-3b68-40ec-a26c-2056189cb460'	System	01 Sep 2020 18:32:22
User entered 'None (1)'	System	01 Sep 2020 18:32:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:24', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'b4501e5b-3b68-40ec-a26c-2056189cb460'	System	01 Sep 2020 18:32:22
User entered 'No (N)'	System	01 Sep 2020 18:32:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:27', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'b4501e5b-3b68-40ec-a26c-2056189cb460'	System	01 Sep 2020 18:32:22
User entered 'No (N)'	System	01 Sep 2020 18:32:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:32', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'b4501e5b-3b68-40ec-a26c-2056189cb460'	System	01 Sep 2020 18:32:22
User entered 'None (1)'	System	01 Sep 2020 18:32:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'b4501e5b-3b68-40ec-a26c-2056189cb460'	System	01 Sep 2020 18:32:22
User entered '01 Sep 2020 13:39'	System	01 Sep 2020 18:32:22

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 7'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '459b7eab-d2bf-4c47-85b7-a293e2cea342'	System	02 Sep 2020 20:18:50
User entered 'None (1)'	System	02 Sep 2020 20:18:50

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '459b7eab-d2bf-4c47-85b7-a293e2cea342'	System	02 Sep 2020 20:18:50
User entered 'No (N)'	System	02 Sep 2020 20:18:50

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:25:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '459b7eab-d2bf-4c47-85b7-a293e2cea342'	System	02 Sep 2020 20:18:50
User entered 'No (N)'	System	02 Sep 2020 20:18:50

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '459b7eab-d2bf-4c47-85b7-a293e2cea342'	System	02 Sep 2020 20:18:50
User entered 'None (1)'	System	02 Sep 2020 20:18:50

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '459b7eab-d2bf-4c47-85b7-a293e2cea342'	System	02 Sep 2020 20:18:50
User entered '02 Sep 2020 15:26'	System	02 Sep 2020 20:18:50

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:57:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:03', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:06', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'None (0)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered 'No (N)'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T17:58:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ff754db8-a38d-402a-9739-1819601e7504'	System	27 Aug 2020 22:51:07
User entered '27 Aug 2020 17:58'	System	27 Aug 2020 22:51:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 17:31'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'None (0)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'None (0)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:00:59', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'None (0)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:01:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'None (0)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:01:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'None (0)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:01:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered 'No (N)'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-27T21:01:15', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '223c83b6-fa0c-43ee-973c-813feb472b8a'	System	28 Aug 2020 01:54:05
User entered '27 Aug 2020 21:01'	System	28 Aug 2020 01:54:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Aug 2020 20:56'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 2'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'None (0)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:13', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'No interference with activity (1)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'No interference with activity (1)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:23', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'None (0)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'None (0)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'None (0)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da'	System	28 Aug 2020 17:24:24
User entered 'No (N)'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-28T12:31:34', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '744d3e67-a8e8-4b04-92ae-9292425d52da' User entered '28 Aug 2020 12:31'	System	28 Aug 2020 17:24:24
	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 3'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:08', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:13', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'None (0)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered 'No (N)'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-29T13:33:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '19421146-cc9b-4141-a3b5-09ffd0ab2a38'	System	29 Aug 2020 18:26:05
User entered '29 Aug 2020 13:33'	System	29 Aug 2020 18:26:05

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 4'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:37', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:39', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:41', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:45', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:47', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'None (0)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered 'No (N)'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-30T15:03:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '82ff65dd-d995-4f6e-b0e1-de63c157d670'	System	30 Aug 2020 19:56:39
User entered '30 Aug 2020 15:03'	System	30 Aug 2020 19:56:39

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 5'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:39', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:41', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:45', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'None (0)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered 'No (N)'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-08-31T12:04:54', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '14b2a5e4-2c99-4a27-85af-ab1d4b90e166'	System	31 Aug 2020 16:59:11
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:59:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 6'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:42', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'None (0)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:56', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered 'No (N)'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-01T13:39:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3d537d46-952b-43cd-ac6e-ee034123681f'	System	01 Sep 2020 18:32:45
User entered '01 Sep 2020 13:39'	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 7'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:06', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:07', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:14', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'None (0)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered 'No (N)'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-02T15:26:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '05936c72-75e8-4795-9cd8-4d23f9ad21e2'	System	02 Sep 2020 20:19:11
User entered '02 Sep 2020 15:26'	System	02 Sep 2020 20:19:11

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:13:07

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:08:29
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Sep 2020 14:51:04

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:44:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Un-verified.	(b) (4)	
	Laura Ngansop Djampou	10 Nov 2020 17:41:22
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	10 Nov 2020 17:41:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:08:29
User entered '3 Sep 2020'	Laura Ngansop Djampou	04 Sep 2020 14:51:04
	(b) (4)	

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:08:29
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	04 Sep 2020 14:51:04

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:29
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Sep 2020 14:51:04

US3212326

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:44
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Sep 2020 14:51:09

US3212326

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	04 Sep 2020 14:51:09

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:20
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:46:28

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:20
User entered '10 Sep 2020'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:46:28

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:20
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:46:28

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:20
User entered empty.	Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:46:28

US3212326

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:24
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:46:35

US3212326

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	11 Sep 2020 15:46:35

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:46
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Sep 2020 19:15:43

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:46
User entered '17 Sep 2020'	Laura Ngansop Djampou (b) (4)	18 Sep 2020 19:15:43

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:46
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	18 Sep 2020 19:15:43

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:46
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Sep 2020 19:15:43

US3212326

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:52
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Sep 2020 19:15:49

US3212326

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	18 Sep 2020 19:15:49

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:18:20
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:22:12

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:18:20
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:22:12

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:18:20
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:22:12

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'VISIT2'	System	25 Sep 2020 20:22:12

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	25 Sep 2020 20:23:07
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '10:04'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '25 Sep 2020 10:04'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '97.8' F	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '81'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'bpm'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '15'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'breaths/min'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '102'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '64'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '11:56'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '25 Sep 2020 11:56'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '97.9' F	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '65'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'bpm'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '14'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'breaths/min'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '98'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '66'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:20:43
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:09

US3212326

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:20:43
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:09

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered empty.	Afifah Ayub (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered '25 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered '11:19'	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '25 Sep 2020 11:19'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:21:22
User entered 'ONCE'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:50:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:21:35
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:37

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:21:35
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:37

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:21:35
User entered '10:40'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:37

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '25 Sep 2020 10:40'	System	25 Sep 2020 20:24:37

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:22:02
User entered '25 Sep 2020'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered '10:36'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '25 Sep 2020 10:36'	System	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered empty.	System	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:22:50
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 20:25:01

US3212326

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	25 Sep 2020 20:25:01

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T11:59:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '29388f2f-f943-475a-a513-6b7c1b32797a'	System	25 Sep 2020 16:52:52
User entered 'Yes (Y)'	System	25 Sep 2020 16:52:52

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '29388f2f-f943-475a-a513-6b7c1b32797a'	System	25 Sep 2020 16:52:52
User entered '97.9'	System	25 Sep 2020 16:52:52

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:13', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '29388f2f-f943-475a-a513-6b7c1b32797a'	System	25 Sep 2020 16:52:52
User entered 'No (N)'	System	25 Sep 2020 16:52:52

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:29', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '29388f2f-f943-475a-a513-6b7c1b32797a'	System	25 Sep 2020 16:52:52
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 16:52:52

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:35', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	System	25 Sep 2020 23:56:19
User entered 'Yes (Y)'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:41', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	System	25 Sep 2020 23:56:19
User entered '100.1'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	System	25 Sep 2020 23:56:19
User entered 'Yes (Y)'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient contacted, conmeds updated' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:57:32
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.'	Heather Leary (b) (4)	28 Sep 2020 19:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	(b) (4)	
User entered '1'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	System	25 Sep 2020 23:56:19
User entered '0'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:03:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5f718f0a-8853-4acd-b92f-8922b8ad4051'	System	25 Sep 2020 23:56:19
User entered '25 Sep 2020 19:03'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 2'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:17:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	System	26 Sep 2020 17:10:31
User entered 'Yes (Y)'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:17:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	System	26 Sep 2020 17:10:31
User entered '101.5'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	System	26 Sep 2020 17:10:31
User entered 'Yes (Y)'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient contacted, conmeds updated' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:57:38
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.'	Heather Leary (b) (4)	28 Sep 2020 19:09:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	(b) (4)	
User entered '1'	System	26 Sep 2020 17:10:31
	System	26 Sep 2020 17:10:31
	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	System	26 Sep 2020 17:10:31
User entered '0'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '01ca612d-7d72-4fd0-ab8f-bff66f4759ce'	System	26 Sep 2020 17:10:31
User entered '26 Sep 2020 12:18'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 3'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '704b12f0-0c77-4621-aa73-302fe8bb7405'	System	27 Sep 2020 19:38:44
User entered 'Yes (Y)'	System	27 Sep 2020 19:38:44

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '704b12f0-0c77-4621-aa73-302fe8bb7405'	System	27 Sep 2020 19:38:44
User entered '98.0'	System	27 Sep 2020 19:38:44

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:15', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '704b12f0-0c77-4621-aa73-302fe8bb7405'	System	27 Sep 2020 19:38:44
User entered 'No (N)'	System	27 Sep 2020 19:38:44

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '704b12f0-0c77-4621-aa73-302fe8bb7405'	System	27 Sep 2020 19:38:44
User entered '27 Sep 2020 14:46'	System	27 Sep 2020 19:38:44

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 4'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:38:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '950c8a29-1f7f-4ba5-ac7e-68a3b0c5b0d3'	System	28 Sep 2020 19:31:28
User entered 'Yes (Y)'	System	28 Sep 2020 19:31:28

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:01', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '950c8a29-1f7f-4ba5-ac7e-68a3b0c5b0d3'	System	28 Sep 2020 19:31:28
User entered '98.2'	System	28 Sep 2020 19:31:28

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '950c8a29-1f7f-4ba5-ac7e-68a3b0c5b0d3'	System	28 Sep 2020 19:31:28
User entered 'No (N)'	System	28 Sep 2020 19:31:28

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:06', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '950c8a29-1f7f-4ba5-ac7e-68a3b0c5b0d3'	System	28 Sep 2020 19:31:28
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 19:31:28

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 5'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:04:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f88e082-e500-46a2-98cf-613cb27175a1'	System	29 Sep 2020 16:57:32
User entered 'Yes (Y)'	System	29 Sep 2020 16:57:32

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f88e082-e500-46a2-98cf-613cb27175a1'	System	29 Sep 2020 16:57:32
User entered '98.2'	System	29 Sep 2020 16:57:32

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:07', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f88e082-e500-46a2-98cf-613cb27175a1'	System	29 Sep 2020 16:57:32
User entered 'No (N)'	System	29 Sep 2020 16:57:32

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1f88e082-e500-46a2-98cf-613cb27175a1'	System	29 Sep 2020 16:57:32
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 16:57:32

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 6'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:06', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ef351319-b352-4808-a304-8633e806ae85'	System	30 Sep 2020 18:35:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:35:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ef351319-b352-4808-a304-8633e806ae85'	System	30 Sep 2020 18:35:39
User entered '98.2'	System	30 Sep 2020 18:35:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:14', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ef351319-b352-4808-a304-8633e806ae85'	System	30 Sep 2020 18:35:39
User entered 'No (N)'	System	30 Sep 2020 18:35:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ef351319-b352-4808-a304-8633e806ae85'	System	30 Sep 2020 18:35:39
User entered '30 Sep 2020 13:43'	System	30 Sep 2020 18:35:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 7'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:48:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a89e4a0b-b30c-4d70-94a9-428050b464cc'	System	01 Oct 2020 21:41:16
User entered 'Yes (Y)'	System	01 Oct 2020 21:41:16

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:48:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a89e4a0b-b30c-4d70-94a9-428050b464cc'	System	01 Oct 2020 21:41:16
User entered '98.1'	System	01 Oct 2020 21:41:16

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:48:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a89e4a0b-b30c-4d70-94a9-428050b464cc'	System	01 Oct 2020 21:41:16
User entered 'No (N)'	System	01 Oct 2020 21:41:16

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:48:54', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'a89e4a0b-b30c-4d70-94a9-428050b464cc'	System	01 Oct 2020 21:41:16
User entered '01 Oct 2020 16:48'	System	01 Oct 2020 21:41:16

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e6de899a-1061-4d55-bf26-e147f0e08f53'	System	25 Sep 2020 16:53:15
User entered 'None (1)'	System	25 Sep 2020 16:53:15

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e6de899a-1061-4d55-bf26-e147f0e08f53'	System	25 Sep 2020 16:53:15
User entered 'No (N)'	System	25 Sep 2020 16:53:15

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e6de899a-1061-4d55-bf26-e147f0e08f53'	System	25 Sep 2020 16:53:15
User entered 'No (N)'	System	25 Sep 2020 16:53:15

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:47', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e6de899a-1061-4d55-bf26-e147f0e08f53'	System	25 Sep 2020 16:53:15
User entered 'None (1)'	System	25 Sep 2020 16:53:15

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e6de899a-1061-4d55-bf26-e147f0e08f53'	System	25 Sep 2020 16:53:15
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 16:53:15

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:04:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:04:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered 'No (N)'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:04:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered 'Yes (Y)'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:04:56', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered '5'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered 'None (1)'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '8412453e-599a-4dd9-8869-5c0e6d5f7073'	System	25 Sep 2020 23:57:30
User entered '25 Sep 2020 19:05'	System	25 Sep 2020 23:57:30

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 2'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered 'No (N)'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:23', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered 'Yes (Y)'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered '4'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:34', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered 'None (1)'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:37', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '16c2425c-f715-4c37-929e-b5df27e8bae7'	System	26 Sep 2020 17:10:59
User entered '26 Sep 2020 12:18'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 3'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ac067ace-c7de-44c5-abd9-bf039e958993'	System	27 Sep 2020 19:39:11
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 19:39:11

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ac067ace-c7de-44c5-abd9-bf039e958993'	System	27 Sep 2020 19:39:11
User entered 'No (N)'	System	27 Sep 2020 19:39:11

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ac067ace-c7de-44c5-abd9-bf039e958993'	System	27 Sep 2020 19:39:11
User entered 'No (N)'	System	27 Sep 2020 19:39:11

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:47', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ac067ace-c7de-44c5-abd9-bf039e958993'	System	27 Sep 2020 19:39:11
User entered 'None (1)'	System	27 Sep 2020 19:39:11

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:49', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ac067ace-c7de-44c5-abd9-bf039e958993'	System	27 Sep 2020 19:39:11
User entered '27 Sep 2020 14:46'	System	27 Sep 2020 19:39:11

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 4'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '962050d9-1bbf-4c00-b38c-b0a6e97b7733'	System	28 Sep 2020 19:31:41
User entered 'None (1)'	System	28 Sep 2020 19:31:41

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:12', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '962050d9-1bbf-4c00-b38c-b0a6e97b7733'	System	28 Sep 2020 19:31:41
User entered 'No (N)'	System	28 Sep 2020 19:31:41

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:14', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '962050d9-1bbf-4c00-b38c-b0a6e97b7733'	System	28 Sep 2020 19:31:41
User entered 'No (N)'	System	28 Sep 2020 19:31:41

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '962050d9-1bbf-4c00-b38c-b0a6e97b7733'	System	28 Sep 2020 19:31:41
User entered 'None (1)'	System	28 Sep 2020 19:31:41

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '962050d9-1bbf-4c00-b38c-b0a6e97b7733'	System	28 Sep 2020 19:31:41
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 19:31:41

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 5'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:15', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '996347e6-15cf-488d-a7b2-fbdcb947663a'	System	29 Sep 2020 16:57:48
User entered 'None (1)'	System	29 Sep 2020 16:57:48

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '996347e6-15cf-488d-a7b2-fbdcb947663a'	System	29 Sep 2020 16:57:48
User entered 'No (N)'	System	29 Sep 2020 16:57:48

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '996347e6-15cf-488d-a7b2-fbdcb947663a'	System	29 Sep 2020 16:57:48
User entered 'No (N)'	System	29 Sep 2020 16:57:48

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:23', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '996347e6-15cf-488d-a7b2-fbdcb947663a'	System	29 Sep 2020 16:57:48
User entered 'None (1)'	System	29 Sep 2020 16:57:48

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '996347e6-15cf-488d-a7b2-fbdc947663a'	System	29 Sep 2020 16:57:48
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 16:57:48

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 6'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '43b7bc2e-5ccb-46ec-a978-eec7cf37578d'	System	30 Sep 2020 18:35:52
User entered 'None (1)'	System	30 Sep 2020 18:35:52

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:24', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '43b7bc2e-5ccb-46ec-a978-eec7cf37578d'	System	30 Sep 2020 18:35:52
User entered 'No (N)'	System	30 Sep 2020 18:35:52

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:26', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '43b7bc2e-5ccb-46ec-a978-eec7cf37578d'	System	30 Sep 2020 18:35:52
User entered 'No (N)'	System	30 Sep 2020 18:35:52

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:28', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '43b7bc2e-5ccb-46ec-a978-eec7cf37578d'	System	30 Sep 2020 18:35:52
User entered 'None (1)'	System	30 Sep 2020 18:35:52

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:30', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '43b7bc2e-5ccb-46ec-a978-eec7cf37578d'	System	30 Sep 2020 18:35:52
User entered '30 Sep 2020 13:43'	System	30 Sep 2020 18:35:52

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 7'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:48:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'be40eaae-f00b-452b-b3d2-568a3019401c'	System	01 Oct 2020 21:41:29
User entered 'None (1)'	System	01 Oct 2020 21:41:29

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'be40eaae-f00b-452b-b3d2-568a3019401c'	System	01 Oct 2020 21:41:29
User entered 'No (N)'	System	01 Oct 2020 21:41:29

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'be40eaae-f00b-452b-b3d2-568a3019401c'	System	01 Oct 2020 21:41:29
User entered 'No (N)'	System	01 Oct 2020 21:41:29

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'be40eaae-f00b-452b-b3d2-568a3019401c'	System	01 Oct 2020 21:41:29
User entered 'None (1)'	System	01 Oct 2020 21:41:29

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:07', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'be40eaae-f00b-452b-b3d2-568a3019401c'	System	01 Oct 2020 21:41:29
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 21:41:29

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:54', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:01:01', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:01:03', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:01:05', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'None (0)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:01:08', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered 'No (N)'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T12:01:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '12a9c9b4-7574-405f-b30d-34aba53538c5'	System	25 Sep 2020 16:53:33
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 16:53:33

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 14:09'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:24', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:35', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'Significant; prevents daily activity (3)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:45', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:05:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'None (0)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:06:14', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'Prevents daily activity and requires medical attention (3)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:06:19', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered 'No (N)'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-25T19:06:27', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ab5d7faf-f38d-4cb3-9855-d9ceb50e75ee'	System	25 Sep 2020 23:58:49
User entered '25 Sep 2020 19:06'	System	25 Sep 2020 23:58:49

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '25 Sep 2020 15:04'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 2'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'Some interference with activity (2)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:18:59', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'Some interference with activity (2)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:19:01', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'Some interference with activity (2)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:19:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'None (0)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:19:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'Some interference with activity not requiring medical attention (2)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:19:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered 'No (N)'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-26T12:19:34', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '0a716290-c681-482a-b9f9-7a895f98f8c4'	System	26 Sep 2020 17:11:55
User entered '26 Sep 2020 12:19'	System	26 Sep 2020 17:11:55

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 3'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:46:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'No interference with activity (1)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'Some interference with activity (2)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:07', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'Some interference with activity (2)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:10', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'Some interference with activity (2)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:12', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'None (0)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'Some interference with activity not requiring medical attention (2)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered 'No (N)'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-27T14:47:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'cae1e660-ee55-4e7f-a6db-90f22fd9e8dd'	System	27 Sep 2020 19:39:44
User entered '27 Sep 2020 14:47'	System	27 Sep 2020 19:39:44

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 4'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:23', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'None (0)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'None (0)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:27', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'None (0)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'No interference with activity (1)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'None (0)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'No interference with activity (1)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:39', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered 'No (N)'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-28T14:39:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '3756b277-2df7-4b94-9c31-16e856482626'	System	28 Sep 2020 19:32:03
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 19:32:03

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 5'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:31', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'None (0)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:39', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'None (0)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'None (0)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'None (0)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered 'No (N)'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-29T12:05:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '9eb38a97-3125-4ab5-b16f-d46f4373dfa6'	System	29 Sep 2020 16:58:18
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 16:58:18

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 6'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:34', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:38', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:41', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:43', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'None (0)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:47', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered 'No (N)'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-09-30T13:43:49', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eef95cf7-2406-4034-906e-ebbf7c2c968b'	System	30 Sep 2020 18:36:10
User entered '30 Sep 2020 13:43'	System	30 Sep 2020 18:36:10

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	25 Sep 2020 16:28:39
User entered 'Day 7'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:13', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:14', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'None (0)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:22', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af'	System	01 Oct 2020 21:41:47
User entered 'No (N)'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-01T16:49:24', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '63d75e57-b8ab-44d8-84bc-2c1f1a9a74af' User entered '01 Oct 2020 16:49'	System	01 Oct 2020 21:41:47
	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:28:39

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:50:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:28:39

US3212326

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:22:57
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 21:48:28

US3212326

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:44:47
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Un-verified.	(b) (4)	
	Laura Ngansop Djampou	10 Dec 2020 19:58:42
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	10 Dec 2020 19:58:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:22:57
User entered '2 Oct 2020'	Laura Ngansop Djampou	05 Oct 2020 21:48:28
	(b) (4)	

US3212326

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:22:57
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 21:48:28

US3212326

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:22:57
User entered empty.	Laura Ngansop Djampou (b) (4)	05 Oct 2020 21:48:28

US3212326

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:23:11
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Oct 2020 21:48:32

US3212326

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	05 Oct 2020 21:48:32

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:22
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Oct 2020 14:23:01

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:44:52
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Un-verified.	(b) (4)	
	Laura Ngansop Djampou	10 Dec 2020 19:58:49
	(b) (4)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	10 Dec 2020 19:58:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:22
User entered '9 Oct 2020'	Laura Ngansop Djampou	14 Oct 2020 14:23:01
	(b) (4)	

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:52:22
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	14 Oct 2020 14:23:01

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:52:22
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Oct 2020 14:23:01

US3212326

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:52:57
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Oct 2020 14:23:07

US3212326

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	14 Oct 2020 14:23:07

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:53
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Oct 2020 16:39:17

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:53
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	19 Oct 2020 16:39:17

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:55:53
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	19 Oct 2020 16:39:17

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:55:53
User entered empty.	Laura Ngansop Djampou (b) (4)	19 Oct 2020 16:39:17

US3212326

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:56:43
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Oct 2020 16:39:26

US3212326

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	19 Oct 2020 16:39:26

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:10:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:44:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:01
User entered '30 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:44:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:10:01
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:44:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'VISIT3'	System	30 Oct 2020 17:44:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '30 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '11:29'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '30 Oct 2020 11:29'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '98.4' F	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '63'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'bpm'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '17'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'breaths/min'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '101'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered '72'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'mmHg'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:43

US3212326

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:09
User entered '30 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:43

US3212326

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:16
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:57

US3212326

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:16
User entered '30 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:57

US3212326

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:16
User entered '12:00'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:45:57

US3212326

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered '30 Oct 2020 12:00'	System	30 Oct 2020 17:45:57

US3212326

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:13:23
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:46:02

US3212326

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	30 Oct 2020 17:46:02

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 64'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-29T13:12:53', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '253ca684-f2f1-4b75-81a9-82eb64915bb8'	System	29 Oct 2020 18:05:08
User entered 'No (N)'	System	29 Oct 2020 18:05:08

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-29T13:12:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '253ca684-f2f1-4b75-81a9-82eb64915bb8'	System	29 Oct 2020 18:05:08
User entered 'No (N)'	System	29 Oct 2020 18:05:08

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-10-29T13:13:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '253ca684-f2f1-4b75-81a9-82eb64915bb8'	System	29 Oct 2020 18:05:08
User entered '29 Oct 2020 13:13:04'	System	29 Oct 2020 18:05:08

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 71'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-03T10:09:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1e77cdcc-4297-43f2-8b27-5cfa4a70b5b8'	System	03 Nov 2020 16:01:58
User entered 'No (N)'	System	03 Nov 2020 16:01:58

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-03T10:09:56', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1e77cdcc-4297-43f2-8b27-5cfa4a70b5b8'	System	03 Nov 2020 16:01:58
User entered 'No (N)'	System	03 Nov 2020 16:01:58

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-03T10:09:59', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '1e77cdcc-4297-43f2-8b27-5cfa4a70b5b8'	System	03 Nov 2020 16:01:58
User entered '03 Nov 2020 10:09:59'	System	03 Nov 2020 16:01:58

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered 'Day 78'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-10T10:45:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '538433b7-a410-4fbb-a2cd-ffa0e1568633'	System	10 Nov 2020 16:37:51
User entered 'No (N)'	System	10 Nov 2020 16:37:51

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-10T10:45:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '538433b7-a410-4fbb-a2cd-ffa0e1568633'	System	10 Nov 2020 16:37:51
User entered 'No (N)'	System	10 Nov 2020 16:37:51

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-10T10:45:52', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '538433b7-a410-4fbb-a2cd-ffa0e1568633' User entered '10 Nov 2020 10:45:52'	System	10 Nov 2020 16:37:51
	System	10 Nov 2020 16:37:51

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 22:13:07

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:23:16
Data entry locked.	System	27 Aug 2020 22:13:07
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 22:13:07

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-11-23T19:16:45', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2e8cb0f3-2cdf-45d0-b175-d725f8a5f08d'	System	24 Nov 2020 01:08:19
User entered 'No (N)'	System	24 Nov 2020 01:08:19

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-11-23T19:16:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2e8cb0f3-2cdf-45d0-b175-d725f8a5f08d'	System	24 Nov 2020 01:08:19
User entered 'No (N)'	System	24 Nov 2020 01:08:19

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-11-23T19:16:51', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2e8cb0f3-2cdf-45d0-b175-d725f8a5f08d'	System	24 Nov 2020 01:08:19
User entered '23 Nov 2020 19:16:51'	System	24 Nov 2020 01:08:19

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-12-01T10:29:57', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ed876b06-23b3-47a2-b233-41eda44b9716'	System	01 Dec 2020 16:21:24
User entered 'No (N)'	System	01 Dec 2020 16:21:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-12-01T10:30:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ed876b06-23b3-47a2-b233-41eda44b9716'	System	01 Dec 2020 16:21:24
User entered 'No (N)'	System	01 Dec 2020 16:21:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-12-01T10:30:04', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'ed876b06-23b3-47a2-b233-41eda44b9716'	System	01 Dec 2020 16:21:24
User entered '01 Dec 2020 10:30:04'	System	01 Dec 2020 16:21:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-12-05T09:20:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'c43aead4-011e-4841-8399-bce988e7edfb'	System	05 Dec 2020 15:12:38
User entered 'No (N)'	System	05 Dec 2020 15:12:38

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-12-05T09:20:47', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'c43aaed4-011e-4841-8399-bce988e7edfb'	System	05 Dec 2020 15:12:38
User entered 'No (N)'	System	05 Dec 2020 15:12:38

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-12-05T09:21:17', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'c43aaed4-011e-4841-8399-bce988e7edfb' User entered '05 Dec 2020 09:21:17'	System	05 Dec 2020 15:12:38
	System	05 Dec 2020 15:12:38

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-12-12T11:02:55', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '57509f56-2ca1-40db-9ec7-8414583930b0'	System	12 Dec 2020 16:54:17
User entered 'No (N)'	System	12 Dec 2020 16:54:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-12-12T11:02:58', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '57509f56-2ca1-40db-9ec7-8414583930b0'	System	12 Dec 2020 16:54:17
User entered 'No (N)'	System	12 Dec 2020 16:54:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-12-12T11:03:01', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '57509f56-2ca1-40db-9ec7-8414583930b0' User entered '12 Dec 2020 11:03:01'	System	12 Dec 2020 16:54:17
	System	12 Dec 2020 16:54:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-12-19T15:00:21', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eeefbb88-ee15-452e-ac4a-31d06152b3c2'	System	19 Dec 2020 20:51:39
User entered 'No (N)'	System	19 Dec 2020 20:51:39

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-12-19T15:00:23', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eeefbb88-ee15-452e-ac4a-31d06152b3c2'	System	19 Dec 2020 20:51:39
User entered 'No (N)'	System	19 Dec 2020 20:51:39

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-12-19T15:00:25', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'eeefbb88-ee15-452e-ac4a-31d06152b3c2'	System	19 Dec 2020 20:51:39
User entered '19 Dec 2020 15:00:25'	System	19 Dec 2020 20:51:39

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2020-12-30T12:04:27', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '30d28593-31f6-473f-90c1-9513bef7d123'	System	30 Dec 2020 17:55:24
User entered 'No (N)'	System	30 Dec 2020 17:55:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2020-12-30T12:04:30', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '30d28593-31f6-473f-90c1-9513bef7d123'	System	30 Dec 2020 17:55:24
User entered 'No (N)'	System	30 Dec 2020 17:55:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2020-12-30T12:04:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '30d28593-31f6-473f-90c1-9513bef7d123'	System	30 Dec 2020 17:55:24
User entered '30 Dec 2020 12:04:33'	System	30 Dec 2020 17:55:24

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2021-01-02T08:34:56', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e5552c80-db16-44bb-aebd-06f7235c89c0'	System	02 Jan 2021 14:25:52
User entered 'No (N)'	System	02 Jan 2021 14:25:52

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2021-01-02T08:34:59', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e5552c80-db16-44bb-aebd-06f7235c89c0'	System	02 Jan 2021 14:25:52
User entered 'No (N)'	System	02 Jan 2021 14:25:52

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2021-01-02T08:35:02', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'e5552c80-db16-44bb-aebd-06f7235c89c0'	System	02 Jan 2021 14:25:52
User entered '02 Jan 2021 08:35:02'	System	02 Jan 2021 14:25:52

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2021-01-09T08:42:44', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd61f3156-99c6-4d1d-acef-d29de51f6ceb'	System	09 Jan 2021 14:33:37
User entered 'No (N)'	System	09 Jan 2021 14:33:37

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2021-01-09T08:42:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd61f3156-99c6-4d1d-acef-d29de51f6ceb'	System	09 Jan 2021 14:33:37
User entered 'No (N)'	System	09 Jan 2021 14:33:37

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2021-01-09T08:42:48', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd61f3156-99c6-4d1d-acef-d29de51f6ceb' User entered '09 Jan 2021 08:42:48'	System	09 Jan 2021 14:33:37
	System	09 Jan 2021 14:33:37

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2021-01-20T12:44:16', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd64efded-d443-4bfa-8f5a-b1b78ac4c553'	System	20 Jan 2021 18:34:48
User entered 'No (N)'	System	20 Jan 2021 18:34:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2021-01-20T12:44:18', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd64efded-d443-4bfa-8f5a-b1b78ac4c553'	System	20 Jan 2021 18:34:48
User entered 'No (N)'	System	20 Jan 2021 18:34:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2021-01-20T12:44:20', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd64efded-d443-4bfa-8f5a-b1b78ac4c553'	System	20 Jan 2021 18:34:48
User entered '20 Jan 2021 12:44:20'	System	20 Jan 2021 18:34:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2021-01-23T09:35:30', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5e405f44-5358-444e-aa47-0daa94718014'	System	23 Jan 2021 15:26:04
User entered 'No (N)'	System	23 Jan 2021 15:26:04

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2021-01-23T09:35:33', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5e405f44-5358-444e-aa47-0daa94718014'	System	23 Jan 2021 15:26:04
User entered 'No (N)'	System	23 Jan 2021 15:26:04

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2021-01-23T09:35:36', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '5e405f44-5358-444e-aa47-0daa94718014' User entered '23 Jan 2021 09:35:36'	System	23 Jan 2021 15:26:04

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (fb6176e70e12ea05)', Time: '2021-02-03T12:43:32', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6e71c916-476c-473f-8262-4227643e0f1b'	System	03 Feb 2021 18:33:55
User entered 'No (N)'	System	03 Feb 2021 18:33:55

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (fb6176e70e12ea05)', Time: '2021-02-03T12:43:37', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6e71c916-476c-473f-8262-4227643e0f1b'	System	03 Feb 2021 18:33:55
User entered 'No (N)'	System	03 Feb 2021 18:33:55

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (fb6176e70e12ea05)', Time: '2021-02-03T12:43:40', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6e71c916-476c-473f-8262-4227643e0f1b' User entered '03 Feb 2021 12:43:40'	System	03 Feb 2021 18:33:55
	System	03 Feb 2021 18:33:55

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-02-06T10:15:06', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '92f01538-aa87-41bd-9ff2-fd4a0f86bc60'	System	06 Feb 2021 16:15:12
User entered 'No (N)'	System	06 Feb 2021 16:15:12

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-02-06T10:15:09', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '92f01538-aa87-41bd-9ff2-fd4a0f86bc60'	System	06 Feb 2021 16:15:12
User entered 'No (N)'	System	06 Feb 2021 16:15:12

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-02-06T10:15:11', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '92f01538-aa87-41bd-9ff2-fd4a0f86bc60'	System	06 Feb 2021 16:15:12
User entered '06 Feb 2021 10:15:11'	System	06 Feb 2021 16:15:12

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-02-20T08:58:42', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2ef38cb8-e4f9-46b4-a2dc-f8e3de982db3'	System	20 Feb 2021 14:58:54
User entered 'No (N)'	System	20 Feb 2021 14:58:54

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-02-20T08:58:46', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2ef38cb8-e4f9-46b4-a2dc-f8e3de982db3'	System	20 Feb 2021 14:58:54
User entered 'No (N)'	System	20 Feb 2021 14:58:54

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-02-20T08:58:50', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2ef38cb8-e4f9-46b4-a2dc-f8e3de982db3' User entered '20 Feb 2021 08:58:50'	System	20 Feb 2021 14:58:54

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-03-03T11:57:08-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6a878a6f-c996-467e-8b34-793c024c7036'	System	03 Mar 2021 17:57:18
User entered 'No (N)'	System	03 Mar 2021 17:57:18

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-03-03T11:57:10-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6a878a6f-c996-467e-8b34-793c024c7036'	System	03 Mar 2021 17:57:18
User entered 'No (N)'	System	03 Mar 2021 17:57:18

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-03T11:57:13-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '6a878a6f-c996-467e-8b34-793c024c7036'	System	03 Mar 2021 17:57:18
User entered '03 Mar 2021 11:57:13'	System	03 Mar 2021 17:57:18

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-03-06T07:29:19-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'fb89d720-f56e-406c-b168-6391d08ad890'	System	06 Mar 2021 13:29:26
User entered 'No (N)'	System	06 Mar 2021 13:29:26

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-03-06T07:29:21-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'fb89d720-f56e-406c-b168-6391d08ad890'	System	06 Mar 2021 13:29:26
User entered 'No (N)'	System	06 Mar 2021 13:29:26

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-06T07:29:24-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'fb89d720-f56e-406c-b168-6391d08ad890'	System	06 Mar 2021 13:29:26
User entered '06 Mar 2021 07:29:24'	System	06 Mar 2021 13:29:26

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-03-13T08:37:31-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '39e02834-8485-4341-9e1c-f6f58d2a26fc'	System	13 Mar 2021 14:37:42
User entered 'No (N)'	System	13 Mar 2021 14:37:42

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-03-13T08:37:36-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '39e02834-8485-4341-9e1c-f6f58d2a26fc'	System	13 Mar 2021 14:37:42
User entered 'No (N)'	System	13 Mar 2021 14:37:42

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-13T08:37:39-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '39e02834-8485-4341-9e1c-f6f58d2a26fc' User entered '13 Mar 2021 08:37:39'	System	13 Mar 2021 14:37:42
	System	13 Mar 2021 14:37:42

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-03-20T08:36:47-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '70c46f01-8d67-4080-b052-2c0b9f014ab5'	System	20 Mar 2021 13:36:58
User entered 'No (N)'	System	20 Mar 2021 13:36:58

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-03-20T08:36:52-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '70c46f01-8d67-4080-b052-2c0b9f014ab5'	System	20 Mar 2021 13:36:58
User entered 'No (N)'	System	20 Mar 2021 13:36:58

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-20T08:36:54-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '70c46f01-8d67-4080-b052-2c0b9f014ab5' User entered '20 Mar 2021 08:36:54'	System	20 Mar 2021 13:36:58
	System	20 Mar 2021 13:36:58

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-03-30T15:22:40-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '427bd36a-2b4e-41ff-b087-300a0a7361b9' User entered 'No (N)'	System	30 Mar 2021 20:22:48
	System	30 Mar 2021 20:22:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-03-30T15:22:42-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '427bd36a-2b4e-41ff-b087-300a0a7361b9'	System	30 Mar 2021 20:22:48
User entered 'No (N)'	System	30 Mar 2021 20:22:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-30T15:22:45-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '427bd36a-2b4e-41ff-b087-300a0a7361b9' User entered '30 Mar 2021 15:22:45'	System	30 Mar 2021 20:22:48
	System	30 Mar 2021 20:22:48

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-04-07T09:30:41-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd322ebc1-1d09-456e-9175-883ecaad5b17'	System	07 Apr 2021 14:30:50
User entered 'No (N)'	System	07 Apr 2021 14:30:50

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-04-07T09:30:44-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd322ebc1-1d09-456e-9175-883ecaad5b17'	System	07 Apr 2021 14:30:50
User entered 'No (N)'	System	07 Apr 2021 14:30:50

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-04-07T09:30:46-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd322ebc1-1d09-456e-9175-883ecaad5b17'	System	07 Apr 2021 14:30:50
User entered '07 Apr 2021 09:30:46'	System	07 Apr 2021 14:30:50

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-04-10T11:43:13-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '735b4280-3d04-4e6b-8072-b221cbf0fd17'	System	10 Apr 2021 16:43:17
User entered 'No (N)'	System	10 Apr 2021 16:43:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-04-10T11:43:15-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '735b4280-3d04-4e6b-8072-b221cbf0fd17'	System	10 Apr 2021 16:43:17
User entered 'No (N)'	System	10 Apr 2021 16:43:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-04-10T11:43:17-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '735b4280-3d04-4e6b-8072-b221cbf0fd17' User entered '10 Apr 2021 11:43:17'	System	10 Apr 2021 16:43:17
	System	10 Apr 2021 16:43:17

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-04-21T09:39:57-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'db720ac5-07f5-4748-9e27-203e5efef445'	System	21 Apr 2021 14:40:05
User entered 'No (N)'	System	21 Apr 2021 14:40:05

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-04-21T09:39:58-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'db720ac5-07f5-4748-9e27-203e5efef445'	System	21 Apr 2021 14:40:05
User entered 'No (N)'	System	21 Apr 2021 14:40:05

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-04-21T09:40:01-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'db720ac5-07f5-4748-9e27-203e5efef445'	System	21 Apr 2021 14:40:05
User entered '21 Apr 2021 09:40:01'	System	21 Apr 2021 14:40:05

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-04-28T11:02:54-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd4b3318d-e5a9-44ff-bbed-10b4eafcb52e' User entered 'No (N)'	System	28 Apr 2021 23:29:20
	System	28 Apr 2021 23:29:20

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-04-28T11:02:56-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd4b3318d-e5a9-44ff-bbed-10b4eafcb52e' User entered 'No (N)'	System	28 Apr 2021 23:29:20
	System	28 Apr 2021 23:29:20

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-04-28T11:02:59-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: 'd4b3318d-e5a9-44ff-bbed-10b4eafcb52e'	System	28 Apr 2021 23:29:20
User entered '28 Apr 2021 11:02:59'	System	28 Apr 2021 23:29:20

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[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 (dbd1ead2cc0c9f3b)', Time: '2021-05-01T08:30:54-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2534f0f2-d2fe-45fc-9e26-75f03cf0553a'	System	01 May 2021 13:31:00
User entered 'No (N)'	System	01 May 2021 13:31:00

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Have you been exposed to someone with 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 (dbd1ead2cc0c9f3b)', Time: '2021-05-01T08:30:56-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2534f0f2-d2fe-45fc-9e26-75f03cf0553a'	System	01 May 2021 13:31:00
User entered 'No (N)'	System	01 May 2021 13:31:00

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-05-01T08:30:58-05:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '2534f0f2-d2fe-45fc-9e26-75f03cf0553a'	System	01 May 2021 13:31:00
User entered '01 May 2021 08:30:58'	System	01 May 2021 13:31:00

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:50:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:31:03

US3212326

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:50:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-03T11:57:21-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '61b8908b-4230-4069-bd59-b2596e916e2a'	System	03 Mar 2021 17:57:26
User entered 'No (N)'	System	03 Mar 2021 17:57:26

US3212326

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:50:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:46:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dbd1ead2cc0c9f3b)', Time: '2021-03-03T11:57:24-06:00', User OID: 'PatientReportedOutcome (US3212326)', ODM File OID: '61b8908b-4230-4069-bd59-b2596e916e2a'	System	03 Mar 2021 17:57:26
User entered '03 Mar 2021 11:57:24'	System	03 Mar 2021 17:57:26

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:09:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:40:23
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Nov 2020 17:17:22

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:09:25
User entered '20 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:40:23
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Nov 2020 17:17:22

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:09:25
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou	23 Nov 2020 14:40:23
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Laura Ngansop Djampou	18 Nov 2020 17:17:22
	(b) (4)	

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:09:25
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Nov 2020 17:17:22

US3212326

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:10:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:40:31

US3212326

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:05:54
User entered 'I'	System	23 Nov 2020 14:40:31

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:00
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Dec 2020 15:09:37

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
User closed query 'Per source, contact was made 04Jan21. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:12:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:52
Query 'Per source, contact was made 04Jan21. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 14:31:04
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:30:49
User entered '04 Jan 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:30:49
User opened query 'Per source, contact was made 04Jan21. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:27:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '23 Dec 2020'	Laura Ngansop Djampou (b) (4)	28 Dec 2020 15:09:37

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:12:32
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:30:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:30:49
User signature succeeded.	(b) (4)	
	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Laura Ngansop Djampou	28 Dec 2020 15:09:37
	(b) (4)	

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:12:50
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:30:49
User entered empty; reason for change Data Entry Error	(b) (4) Heather Leary (b) (4)	15 Apr 2021 14:30:49
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Called subject back at requested time, no answer, left a voicemail.'	(b) (4) Laura Ngansop Djampou	28 Dec 2020 15:09:37

US3212326

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:05
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Dec 2020 15:09:25

US3212326

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User entered 'I'	System	28 Dec 2020 15:09:25

US3212326

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Jan 2021 15:15:23

US3212326

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18NOV2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 07:38:00
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18NOV2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'please enter query on relevant data page, this is a lab query for a safety call. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Feb 2021 21:41:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 18NOV2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 04:32:55
User entered '22 Jan 2021'	Laura Ngansop Djampou (b) (4)	25 Jan 2021 15:15:23

US3212326

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Jan 2021 15:15:23

US3212326

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Jan 2021 15:15:23

US3212326

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:17
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Jan 2021 15:15:34

US3212326

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User entered 'I'	System	25 Jan 2021 15:15:34

US3212326

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	23 Feb 2021 17:12:05

US3212326

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '22 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	23 Feb 2021 17:12:05

US3212326

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	23 Feb 2021 17:12:05

US3212326

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	23 Feb 2021 17:12:05

US3212326

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:39
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	23 Feb 2021 17:11:57

US3212326

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:04
User entered 'I'	System	23 Feb 2021 17:11:57

US3212326

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:35

US3212326

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '26 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:35

US3212326

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinic (Clinic)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:35

US3212326

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'VISIT4'	System	29 Mar 2021 21:11:35

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '26 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '10:15'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered '26 Mar 2021 10:15'	System	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '97.4' F	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '65'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'bpm'	System	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '15'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'breaths/min'	System	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '114'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'mmHg'	System	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:02
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '81'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'mmHg'	System	29 Mar 2021 21:11:59

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04

US3212326

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04

US3212326

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:06
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:09

US3212326

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:06
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '26 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:09

US3212326

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:11
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:23

US3212326

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:11
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '26 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:23

US3212326

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:11
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '10:45'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:23

US3212326

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered '26 Mar 2021 10:45'	System	29 Mar 2021 21:12:23

US3212326

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	29 Mar 2021 21:12:29

US3212326

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:04
User entered 'I'	System	29 Mar 2021 21:12:29

US3212326

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 13:52:03

US3212326

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
User entered '21 Apr 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 13:52:03

US3212326

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 13:52:03

US3212326

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:50:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 13:52:03

US3212326

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 13:51:51

US3212326

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:50:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 13:51:51

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:53
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:28

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:53
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '10:08'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:28

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:53
User entered '18 Nov 2020 10:08'	System	31 Mar 2021 17:43:28

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:53
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:28

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:53
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:28

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'l'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
User entered empty.	System	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:59
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:38

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit .Kindly review and confirm in your query response, if swab sample collected on 18-NOV-2020 was to analyse illness visit or COVID symptoms. If yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error. Thank you.	(b) (4), (b) (6)	09 Apr 2021 11:43:32
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit .Kindly review and confirm in your query response, if swab sample collected on 18-NOV-2020 was to analyse illness visit or COVID symptoms. If yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error. Thank you.	Jagruti Patel (b) (4) (b) (4)	07 Apr 2021 21:42:06
' answered with 'unscheduled visit was done to evaluate the ongoing symptoms as per investigator's request and to collect nasal swab. ' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit .Kindly review and confirm in your query response, if swab sample collected on 18-NOV-2020 was to analyse illness visit or COVID symptoms. If yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error. Thank you.	(b) (4), (b) (6)	07 Apr 2021 15:19:58
' (Site from DM).		

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
	(b) (4)	
User entered '18 Nov 2020'	Afifah Ayub (b) (4)	31 Mar 2021 17:43:56
	(b) (4)	

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Afifah Ayub (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:10:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:21:06
User entered '0'	System	31 Mar 2021 17:43:56

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:52:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "the data is entered and has been since 01DEC2020"; however, no data updates are reflected as there is no provision to capture swab data in unscheduled visit eCRF. Kindly review if swab sample was collected on 18-NOV-2020, if yes, consider initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:00:41
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "the data is entered and has been since 01DEC2020"; however, no data updates are reflected as there is no provision to capture swab data in unscheduled visit eCRF. Kindly review if swab sample was collected on 18-NOV-2020, if yes, consider initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and update swab data in Covid Diagnostic Test eCRF, else clarify.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	31 Mar 2021 17:55:22
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "the data is entered and has been since 01DEC2020"; however, no data updates are reflected as there is no provision to capture swab data in unscheduled visit eCRF. Kindly review if swab sample was collected on 18-NOV-2020, if yes, consider initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:09:47

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Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is reported under Unscheduled visit in PPD portal; however, swab sample 18-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate by initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:42:50
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is reported under Unscheduled visit in PPD portal; however, swab sample 18-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate by initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify.' answered with 'the data is entered and has been since 01DEC2020' (Site from DM).	Reagan Reed (b) (4)	01 Mar 2021 18:52:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-NOV-2020 is reported under Unscheduled visit in PPD portal; however, swab sample 18-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate by initiating separate Covid - 19 Assessment eCRF for 18-NOV-2020 and updating swab data in Covid Diagnostic Test eCRF as there is no provision to capture Unscheduled sample in Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 07:39:05
User entered '20 Oct 2020'	Afifah Ayub (b) (4)	21 Oct 2020 15:51:44

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Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:52:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '15:33'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:51:44

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:14
User entered '20 Oct 2020 15:33'	System	21 Oct 2020 15:51:44

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:52:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:51:44

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Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:50:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:52:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:51:44

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Day 1 (Day 1)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:22:49
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:22:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered '99'	Afifah Ayub (b) (4)	21 Oct 2020 15:54:35
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User entered '%'	System	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:22:53
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered '98.6' F	Afifah Ayub (b) (4)	21 Oct 2020 15:54:35
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
User closed query 'Per source, shortness of breath began 19Oct21. Please verify and update accordingly. ' (Site from CRA).	(b) (4)	16 Apr 2021 17:11:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:16
Query 'Per source, shortness of breath began 19Oct21. Please verify and update accordingly. ' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 14:46:43
DataPoint Un-verified.	(b) (4)	15 Apr 2021 14:46:26
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:46:26
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	15 Apr 2021 14:46:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User opened query 'Per source, shortness of breath began 19Oct21. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 02:31:52
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Moderate (Moderate)'	(b) (4)	21 Oct 2020 15:54:35
	Afifah Ayub (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:22:47
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Mild (Mild)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
User entered 'Day 2 (Day 2)'	(b) (4)	
	Afifah Ayub (b) (4)	22 Oct 2020 15:16:40
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:20:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '21 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:20:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:20:11
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '99'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User entered '%'	System	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:19:27
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '97.4' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:20:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Mild (Mild)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:20:41
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Mild (Mild)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:21:16
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
User entered 'Day 3 (Day 3)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:34:13
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:48
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '22 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:01:11
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:50
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '99'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User entered '%'	System	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:45
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '98.2' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:01:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Mild (Mild)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:01:26
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Mild (Mild)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:56
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Day 2 (Day 2)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '19 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'l'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User entered empty.	System	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:00:21
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Day 3 (Day 3)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered '1'	(b) (4)	
	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	(b) (4)	
	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
User entered '%'	System	03 Nov 2020 21:37:01
User entered empty.	System	27 Oct 2020 15:31:31

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	(b) (4)	
	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	(b) (4) Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:18:38
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 02:18:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	(b) (4) Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:50:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:12:36
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31
	(b) (4)	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 08:20:33
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:55:13
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'will update later.' (Site from System).	Afifah Ayub (b) (4)	21 Oct 2020 15:54:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:54:52
User entered empty.	Afifah Ayub (b) (4)	21 Oct 2020 15:54:52
	(b) (4)	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Afifah Ayub (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:53:51
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:50:27

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:23
User entered '0'	System	26 Oct 2020 16:55:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:50:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:20:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:54:03
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	04 Dec 2020 14:29:33
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	21 Oct 2020 15:55:03
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '22 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:50:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:50:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:59
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:56:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:56:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:56:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered 'SICKD1'	System	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '14:37'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered '20 Oct 2020 14:37'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4)	21 Oct 2020 15:55:53
DataPoint set to visible.	(b) (4) System	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4)	21 Oct 2020 15:55:53
DataPoint set to visible.	(b) (4) System	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '98.6' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Oral (Oral)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '73'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered 'bpm'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '16'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered 'breaths/min'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '110'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered 'mmHg'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '70'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
User entered 'mmHg'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:33
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:00

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:57:33
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:00

US3212326

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:50:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:06

US3212326

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:08
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '20 Oct 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:06

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:19
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:19
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:19
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:22
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:25
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:18

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:25
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:18

US3212326

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:50:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:28
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:27

US3212326

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:50:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:58:28
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:27

US3212326

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

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:47:51

US3212326

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

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:47:51

US3212326

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

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Clinic (Clinic)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:47:51

US3212326

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

Form: Visit Date

Generated On: 09 Jun 2021 15:50:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 17:47:51

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:36:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:30:21
User entered '0'	Heather Leary (b) (4)	22 Apr 2021 15:35:49
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:13:31

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Insiya Valika (b) (4) (b) (4)	23 Apr 2021 19:50:02 22 Apr 2021 19:36:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:30:00
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 15:36:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4) (b) (4)	22 Apr 2021 15:35:49
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6) System	22 Apr 2021 06:17:57 06 Mar 2021 07:13:31

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:30:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User entered empty.	System	28 Jan 2021 17:48:21

US3212326

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

Form: Unblinding

Generated On: 09 Jun 2021 15:50:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User entered empty.	System	28 Jan 2021 17:48:21

US3212326

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:40

US3212326

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:40

US3212326

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:01
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '15:55'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:40

US3212326

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User entered '27 Jan 2021 15:55'	System	28 Jan 2021 17:48:40

US3212326

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:10
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:51

US3212326

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:50:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:10
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '27 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:51

US3212326

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:31:10
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '15:50'	(b) (4) Laura Ngansop Djampou (b) (4)	28 Jan 2021 17:48:51

US3212326

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:11
User entered '27 Jan 2021 15:50'	System	28 Jan 2021 17:48:51

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:46:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '03 Dec 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:45:47

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:46:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:45:47

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:46:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:45:47

US3212326

Folder: **Unscheduled 03 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 15:50:27**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:46:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:45:47

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:46:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:45:47

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:51:33
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:51:35
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '03 Dec 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
User closed query 'Per source, time is 09:48. Please verify and update accordingly.' (Site from CRA).	(b) (4)	16 Apr 2021 17:14:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:14:16
Query 'Per source, time is 09:48. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 14:49:50
Signature has been broken.	(b) (4)	15 Apr 2021 14:49:35
User entered '09:48' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:49:35
User opened query 'Per source, time is 09:48. Please verify and update accordingly.' (Site from CRA).	(b) (4)	15 Apr 2021 14:47:28
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '09:50'	(b) (4)	04 Dec 2020 14:46:19
	Afifah Ayub (b) (4)	
	(b) (4)	

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User entered '03 Dec 2020 09:48'	System	15 Apr 2021 14:49:35
User entered '03 Dec 2020 09:50'	System	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:51:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '97.3' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:51:42
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Oral (Oral)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:51:44
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:52:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '67'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User entered 'bpm'	System	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:52:49
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '13'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User entered 'breaths/min'	System	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:52:52
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '106'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User entered 'mmHg'	System	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:52:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '65'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34
User entered 'mmHg'	System	04 Dec 2020 14:46:19

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:34

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:40
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:53:07
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:27

US3212326

Folder: Unscheduled 03 Dec 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:40
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:53:07
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '03 Dec 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 14:46:27

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:38:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:13:45
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'added' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	01 Dec 2020 19:04:55
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:22:43
User entered '18 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: **Unscheduled 18 Nov 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 15:50:27**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:38:43
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'l'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:38:45
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:08
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4)	16 Apr 2021 17:13:58
User closed query 'Per source and lab portal, no blood sample was collected during this visit. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:13:45
Query 'Per source and lab portal, no blood sample was collected during this visit. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 14:51:10
Signature has been broken.	(b) (4)	15 Apr 2021 14:50:55
User entered '0' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:50:55
User opened query 'Per source and lab portal, no blood sample was collected during this visit. Please verify and update accordingly.' (Site from CRA).	(b) (4)	15 Apr 2021 14:38:34
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '1' reason for change: Data Entry Error	(b) (4)	01 Dec 2020 19:04:29
User entered '0'	Afifah Ayub (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:50:27

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:38:47
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '10:10'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
User entered '18 Nov 2020 10:10'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '98.4' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Oral (Oral)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '86'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
User entered 'bpm'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '15'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
User entered 'breaths/min'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '108'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
User entered 'mmHg'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:31
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '73'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13
User entered 'mmHg'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13

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Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:50:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:13

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Folder: **Unscheduled 18 Nov 2020**

Form: **Physical Examination**

Generated On: **09 Jun 2021 15:50:27**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:58

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Folder: Unscheduled 18 Nov 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:50:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:37:40
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '18 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:58

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Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:13:22
User closed query 'Per source, no blood sample was collected on this day, only PCR Swab. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:13:09
Query 'Per source, no blood sample was collected on this day, only PCR Swab. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 14:48:06
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:47:52
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:47:52
User opened query 'Per source, no blood sample was collected on this day, only PCR Swab. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 14:31:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Dec 2020 19:04:46

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Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4)	16 Apr 2021 17:13:22
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:47:52
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:47:52
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Per response, since the sample is still missing in PPD, the tracking number information is also needed along with the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response. Thank you.' (Site from DM).	(b) (4)	01 Feb 2021 12:03:58
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Per response, since the sample is still missing in PPD, the tracking number information is also needed along with the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response. Thank you.' answered with 'if a result has been generate the sample has been received, please see the lab portal. ' (Site from DM).	Reagan Reed (b) (4)	29 Jan 2021 17:58:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Per response, since the sample is still missing in PPD, the tracking number information is also needed along with the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:09:05

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Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18NOV2020 Unscheduled.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:09:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18NOV2020 Unscheduled.' answered with 'Accession number: 1F60CUJ this sample is in PPD Lab portal and has even generated a result. The sample has been received. No tracking necessary as the result is clearly in portal. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	22 Jan 2021 18:22:56
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18NOV2020 Unscheduled.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:12:18
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18nov2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 20:48:37

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Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18nov2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number 1F60CUJ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18nov2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). User entered '18 Nov 2020'	Reagan Reed (b) (4) (b) (4) (b) (4), (b) (6) Afifah Ayub (b) (4) (b) (4)	11 Dec 2020 14:32:23 11 Dec 2020 12:58:49 01 Dec 2020 19:04:46

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:13:22
Signature has been broken.	Heather Leary (b) (4)	15 Apr 2021 14:47:52
User entered empty; reason for change Data Entry Error	(b) (4) Heather Leary (b) (4)	15 Apr 2021 14:47:52
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '12:35'	(b) (4) Afifah Ayub (b) (4)	01 Dec 2020 19:04:46
	(b) (4)	

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Folder: Unscheduled 18 Nov 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:23
User entered empty.	System	15 Apr 2021 14:47:52
User entered '18 Nov 2020 12:35'	System	01 Dec 2020 19:04:46

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:50:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:57:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:33
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:12:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Pansinusitis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:29:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:29:56
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 15:29:18
DataPoint Un-verified.	Reagan Reed (b) (4)	23 Nov 2020 15:29:10
	(b) (4)	
Coding entries removed.	Reagan Reed (b) (4)	23 Nov 2020 15:29:10
	(b) (4)	
User entered 'acute non-recurrent pansinusitis' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 15:29:10
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 12:48:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 12:48:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:07
Data point term sent to Coder	System	20 Nov 2020 20:46:19
Coding entries removed.	Reagan Reed (b) (4)	20 Nov 2020 20:45:53
	(b) (4)	
User entered 'Possible SINUS INFECTION' reason for change: Data Entry Error	Reagan Reed (b) (4)	20 Nov 2020 20:45:53
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 18:03:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 18:03:55
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	30 Oct 2020 18:02:24
User entered 'Sinus Infection'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:08
User entered 'Yes (Y)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:08
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 20:55:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:15
User entered 'No (N)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:19
User entered 'No (N)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:42
User entered '23 Oct 2020'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:44
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User entered empty.	System	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:46
User entered 'No (N)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:58:24
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	10 Dec 2020 19:59:17
User entered '02 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	10 Dec 2020 19:59:17
User closed query 'Per source, end date is 02Nov20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:48:17
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:14
Query 'Per source, end date is 02Nov20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Reagan Reed (b) (4)	23 Nov 2020 14:36:19
DataPoint Un-verified.	Reagan Reed (b) (4)	23 Nov 2020 14:36:14
User entered '2 Nov 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 14:36:14
User opened query 'Per source, end date is 02Nov20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:41:27
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:40
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:59:41
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	30 Oct 2020 18:59:41
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:59:41
User entered '30 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:59:41
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:01:59

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 18:01:59
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:48
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User entered empty.	System	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:52
User entered 'No (N)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:22
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:27
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:24
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:29
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:30
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:32
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:34
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:35
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:37
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:38
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:40
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:41
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:25
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) (6)	23 Nov 2020 20:31:46
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:44:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 15:43:54
	(b) (4)	
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 05:52:44
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Per source, action was 'not applicable'. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:46:44
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:46:42
Query 'Per source, action was 'not applicable'. Please verify and update accordingly.' answered with 'updated per source' (Site from CRA).	Reagan Reed (b) (4)	20 Nov 2020 21:02:45
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	20 Nov 2020 21:02:02
	(b) (4)	
User opened query 'Per source, action was 'not applicable'. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 20:57:32
User entered 'None (NONE)'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:06
User entered '0' reason for change: Data Entry Error	Laura Ngansop Djampou	30 Oct 2020 18:02:09
	(b) (4)	
User entered '1'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:54:07
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated conmeds' (Site from DM).	Heather Leary (b) (4)	15 Jan 2021 19:47:30
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:25:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:04
User entered '1' reason for change: Data Entry Error	Laura Ngansop Djampou	30 Oct 2020 18:02:09
	(b) (4)	
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:36
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:41
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:44
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 18:01:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User entered '0'	System	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09
User entered '1'	System	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 20:53:38
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'see illness tab' (Site from DM).	Reagan Reed (b) (4)	21 Dec 2020 19:15:45
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 23:11:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 14:53:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 14:53:59
Data point term sent to Coder	System	19 Nov 2020 14:52:41
User entered 'post-nasal drip'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:02
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:41
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:15
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:04
User entered '25 Oct 2020'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:17
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User entered empty.	System	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:58:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:20
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:59:00
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:21
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:23
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User entered empty.	System	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:27
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:29
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:31
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:32
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:35
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:36
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:38
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:40
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:41
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:43
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:06
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:46
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:59:09
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	System Reagan Reed (b) (4)	21 Dec 2020 19:17:15
User entered '1' reason for change: Data Entry Error	Reagan Reed (b) (4)	21 Dec 2020 19:17:15
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	System (b) (4), (b) (6)	21 Dec 2020 19:17:09
User entered '0'	Afifah Ayub (b) (4)	20 Nov 2020 20:59:21
	(b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:59:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
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)	22 Dec 2020 09:06:29
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 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	21 Dec 2020 19:17:21
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	21 Dec 2020 19:17:09
User entered '0' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	21 Dec 2020 19:17:09
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)	08 Dec 2020 02:05:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:23
User entered '1'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:25
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:59:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Afifah Ayub (b) (4)	11 Jan 2021 01:42:20
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:29
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:31
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 14:52:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User entered '0'	System	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13
User entered '1'	System	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:13

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:17:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:08
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	21 Nov 2020 17:01:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm the relationship to IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:43:14
Query 'Per MM: Please confirm the relationship to IP and update, as appropriate. ' answered with 'Per PI Her symptoms of fatigue, dizziness, and palpitations are possibly related to the study product' (Site from DM).	Heather Leary (b) (4) (b) (4)	12 Apr 2021 15:19:58
User opened query 'Per MM: Please confirm the relationship to IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:24
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Autonomic nervous system disorders, PT: Autonomic nervous system imbalance, LLT: Autonomic dysfunction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:41:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:41:56
Data point term sent to Coder	System	19 Nov 2020 21:41:24
User entered 'Autonomic Dysfunction'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:26
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:49:03
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:41
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:06:40
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'PV Query: Please clarify event start date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020).' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:25:29
Query 'PV Query: Please clarify event start date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020).' answered with 'updated' (Site from Safety).	Jagruti Patel (b) (4)	05 Apr 2021 18:24:20
DataPoint Un-verified.	Jagruti Patel (b) (4)	05 Apr 2021 18:22:38
User entered '25 Sep 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 18:22:38
User opened query 'PV Query: Please clarify event start date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020).' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:32:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:51
User entered '18 Oct 2020'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:06:44
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 18:24:11
DataPoint Un-verified.	Jagruti Patel (b) (4)	05 Apr 2021 18:24:11
User entered '17:00' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 18:24:11
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 18:22:38
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:54
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 17:00'	System	05 Apr 2021 18:24:11
User entered empty.	System	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:06:47
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
User entered 'No (N)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:55
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:06:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
User entered '01 Mar 2021' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:57
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:06:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 18:24:11
DataPoint Un-verified.	Jagruti Patel (b) (4)	05 Apr 2021 18:24:11
User entered '15:00' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 18:24:11
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 18:22:38
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:59
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:27:03
User entered '01 Mar 2021 15:00'	System	05 Apr 2021 18:24:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:18:26
User entered empty.	System	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:00
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:43:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Nov 2020 21:43:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:40:37
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
	(b) (4), (b) (6)	19 Jan 2021 15:23:44
User closed query 'URGENT PV Query: Please provide PI's rationale for considering the event of "Autonomic dysfunction" as serious/medically important.' (Site from Safety).	(b) (4), (b) (6)	18 Jan 2021 18:57:59
Query 'URGENT PV Query: Please provide PI's rationale for considering the event of "Autonomic dysfunction" as serious/medically important.' answered with 'Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions as per Section 8.3.3.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:13:43
User opened query 'URGENT PV Query: Please provide PI's rationale for considering the event of "Autonomic dysfunction" as serious/medically important.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:29:04
DataPoint Verified.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:55
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:56
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:59
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:30:01
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:30:03
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:01
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:03
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	20 Nov 2020 20:31:08
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:09
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:20
User entered 'I'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
	(b) (4), (b) (6)	19 Jan 2021 15:23:47
User closed query 'URGENT PV Query: Please provide any additional considerations or evidence, beyond a temporal association, that contributed to the PI's assessment that the event of "Autonomic dysfunction" was related to study drug. If none, please state so.' (Site from Safety).		
Query 'URGENT PV Query: Please provide any additional considerations or evidence, beyond a temporal association, that contributed to the PI's assessment that the event of "Autonomic dysfunction" was related to study drug. If none, please state so.'	(b) (4), (b) (6)	18 Jan 2021 19:01:18
answered with 'Her symptoms have not been identified to have any other cause despite medical check ups with physicians ' (Site from Safety).		
User opened query 'URGENT PV Query: Please provide any additional considerations or evidence, beyond a temporal association, that contributed to the PI's assessment that the event of "Autonomic dysfunction" was related to study drug. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:13:58
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:23
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:43:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Nov 2020 21:43:37
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:40:37
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
	(b) (4), (b) (6)	24 Nov 2020 21:42:34
User closed query 'Per Progress note in source, AE is 'not related' to study procedure. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:42:32
DataPoint Verified.	Reagan Reed (b) (4)	24 Nov 2020 14:50:29
Query 'Per Progress note in source, AE is 'not related' to study procedure. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	(b) (4)	24 Nov 2020 14:50:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 22:50:10
User opened query 'Per Progress note in source, AE is 'not related' to study procedure. Please verify and update accordingly.' (Site from CRA).	System	19 Nov 2020 21:43:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	Afifah Ayub (b) (4)	19 Nov 2020 21:43:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	System	19 Nov 2020 21:40:37
User opened query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
User entered empty.	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:27
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:43:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Nov 2020 21:43:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:40:37
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:33:06
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:33:12
User entered 'I'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:19
User entered '0'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37
	(b) (4)	

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Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:05
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 12:55:35
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jagruti Patel (b) (4)	23 Mar 2021 20:32:47
DataPoint Un-verified.	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:18:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:22
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:43:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:43:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Nov 2020 21:43:37
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:40:37
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:07
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
User entered 'Palpitations' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 20:32:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:26
User entered empty.	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:11
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:10
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'PV Query: Please clarify end date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020). ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:35:28
Query 'PV Query: Please clarify end date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020). ' answered with 'the end date for this is captured here in the eCRF. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	01 Apr 2021 16:23:06
User opened query 'PV Query: Please clarify end date as medical records report that symptoms started while driving home from receiving second dose of vaccine (per source document, 25 Sep 2020). ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 15:26:07
User closed query 'PV Query: Please send documentation with results of all laboratory and diagnostic tests mentioned in the narrative and any office visit notes, with patient identifiers redacted and subject ID added on each page, 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)	23 Mar 2021 14:49:28
User closed query 'PV Query: Please send cardiology and neurology consult notes and/or 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)	23 Mar 2021 14:49:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CXR WAS NORMAL. LABS ARE NORMAL INCLUDING TSH, CBC, CHEMISTRIES, AST, ALT, AND D-DIMER. EKG WAS NORMAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:08:17
User closed query 'Per DM CLR: SAE Narrative = MRI BRAIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:07:54
User closed query 'Per DM CLR: SAE Narrative = HALLPIKE MANEUVER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:07:17
Query 'Per DM CLR: SAE Narrative = MRI BRAIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MRI Brain is added as appropriate' (Site from DM).	Jagruti Patel (b) (4)	22 Mar 2021 14:30:38
Query 'Per DM CLR: SAE Narrative = CXR WAS NORMAL. LABS ARE NORMAL INCLUDING TSH, CBC, CHEMISTRIES, AST, ALT, AND D-DIMER. EKG WAS NORMAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' answered with 'CXR and EKG are added as appropriate' (Site from DM).	Jagruti Patel (b) (4)	22 Mar 2021 14:30:20
Query 'PV Query: Please send documentation with results of all laboratory and diagnostic tests mentioned in the narrative and any office visit notes, with patient identifiers redacted and subject ID added on each page, 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 'records sent' (Site from Safety).	Jagruti Patel (b) (4)	22 Mar 2021 14:11:59

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send cardiology and neurology consult notes and/or 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 'records sent' (Site from Safety).	Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:02:04
User closed query 'Per DM CLR: SAE Narrative = SHE REPORTS HAVING NORMAL THYROID TEST AND OTHER BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	22 Mar 2021 11:17:35
Query 'Per DM CLR: SAE Narrative = HALLPIKE MANEUVER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'HALLPIKE MANEUVER is not a concomitant procedure' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 20:00:03
Query 'Per DM CLR: SAE Narrative = SHE REPORTS HAVING NORMAL THYROID TEST AND OTHER BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Routine blood work is not recorded as a concomitant procedure' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Mar 2021 19:55:57
User opened query 'Per DM CLR: SAE Narrative = HALLPIKE MANEUVER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	08 Dec 2020 02:05:30
User opened query 'Per DM CLR: SAE Narrative = MRI BRAIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	08 Dec 2020 02:05:24
User opened query 'Per DM CLR: SAE Narrative = CXR WAS NORMAL. LABS ARE NORMAL INCLUDING TSH, CBC, CHEMISTRIES, AST, ALT, AND D-DIMER. EKG WAS NORMAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	08 Dec 2020 02:05:15

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SHE REPORTS HAVING NORMAL THYROID TEST AND OTHER BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:05:06
Query 'PV query: Please provide results of COVID-19 testing and dates of testing.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:33:08
User opened query 'PV Query: Please send documentation with results of all laboratory and diagnostic tests mentioned in the narrative and any office visit notes, with patient identifiers redacted and subject ID added on each page, 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)	24 Nov 2020 21:28:40
User opened query 'PV Query: Please send cardiology and neurology consult notes and/or 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)	24 Nov 2020 20:18:52
User opened query 'PV query: Please provide results of COVID-19 testing and dates of testing.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:18:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:29

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported symptoms of intermittent palpitations and intermittent dizziness started in late October about 3 weeks after the second vaccination. She is unable to tolerate her usual level of activity/exercise. In the past she was able to run 10 miles without problems. Recently, she could run only a mile. Lately, if she walks a block, she will develop heart palpitations (heart pounding) and dizziness. She denies any spinning sensation recently. She reports having normal thyroid test and other blood work. No reported syncope or depression. She was referred to a cardiologist and for a holter monitor, but she hasn't done these yet. She finished antibiotics for possible sinus infection. She continues to have symptoms of fatigue and dizziness that limit her exercise and activities. CXR was normal. Labs are normal including TSH, CBC, chemistries, AST, ALT, and D-dimer. EKG was normal-we did on site (18Nov2020). She has intermittent dizziness and vertigo often precipitated by exercise. MRI brain showed no acute changes-CSF collection at the R cerebellomedullary angle suggestive of an arachnoid cyst. Hallpike maneuver was negative- no nystagmus (she was briefly dizzy) bp/pulse tilt: 118/79 pulse 71 lying; 111/77 pulse 76 standing; no tilt; COVID swab done on 19Nov2020 to evaluate for possible long COVID syndrome. Her symptoms of fatigue, dizziness, and palpitations are possibly related to the study product. The symptoms are temporally related. She was referred to get a holter monitor and cardiology evaluation by her doctor. She was thinking of postponing this due to cost since she has high deductible insurance. She thinks her symptoms are related to the study treatment and wants assistance with the cost of this work up. I encouraged her to get further evaluation with the cardiologist/ holter monitoring and possibly neurology.'	Afifah Ayub (b) (4)	19 Nov 2020 21:40:37

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Per MM, this subject presented with post nasal drip (onset 25Oct2020) and fatigue (onset 20Oct2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 08:51:47
Query 'Per MM, this subject presented with post nasal drip (onset 25Oct2020) and fatigue (onset 20Oct2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'please see illness visit tab before issuing such queries. all information is captured there. DO not waste the sites time because you will not open the illness visit tab.' (Site from DM).	Reagan Reed (b) (4)	01 Mar 2021 18:09:59
User opened query 'Per MM, this subject presented with post nasal drip (onset 25Oct2020) and fatigue (onset 20Oct2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 18:27:25
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:35:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:12:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:12:03
Data point term sent to Coder	System	04 Dec 2020 17:10:51
User entered 'fatigue'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:26
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:16:38
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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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)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:42
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:45
User entered '20 Oct 2020'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:46
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User entered empty.	System	04 Dec 2020 17:09:53

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:39
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:49
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:52
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:53
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User entered empty.	System	04 Dec 2020 17:09:53

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:36:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:05
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:06
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:11
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:13
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:14
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:16
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:18
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:19
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:20
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:22
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:25
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:31
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:16:44
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:40
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:44
User entered 'I'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:46
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:54
DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:52
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:49
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:07:46
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Afifah Ayub (b) (4)	11 Jan 2021 01:43:28
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:37:58
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:38:01
User entered empty.	Afifah Ayub (b) (4)	04 Dec 2020 17:09:53
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User entered '0'	System	04 Dec 2020 17:09:53

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20
User entered '1'	System	04 Dec 2020 17:09:53

US3212326

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:20

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per source, subject also had an AE of 'Frequent Menstruation. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:07:46
Query 'Per source, subject also had an AE of 'Frequent Menstruation. Please verify and update accordingly.' answered with 'added' (Site from CRA).	Heather Leary (b) (4)	15 Apr 2021 16:45:40
User opened query 'Per source, subject also had an AE of 'Frequent Menstruation. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:21:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:11:32
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitations aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 20:36:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 20:36:44
Data point term sent to Coder	System	23 Mar 2021 20:36:10
User entered 'Intermittent Palpitations'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:11:35
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'No (N)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:40
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'No (N)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:37
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'No (N)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '01 Mar 2021'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:46
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:48
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'Yes (Y)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:50
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:53
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:13:58
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:02
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'No (N)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:05
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:08
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:10
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:12
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:15
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:18
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:20
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:22
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:24
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:26
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:30
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'Related (RELATED)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per source, 'not related' please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:11:42
	(b) (4), (b) (6)	17 Apr 2021 00:11:38
Query 'Per source, 'not related' please verify and update accordingly.' answered with 'corrected source' (Site from CRA).	Heather Leary (b) (4)	16 Apr 2021 18:51:16
User opened query 'Per source, 'not related' please verify and update accordingly.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 17:09:43
	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 20:36:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 20:36:14
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 20:36:14
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 20:35:30
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:14:47
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'Not Applicable (NOT APPLICABLE)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:15:11
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'I'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:15:21
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:15:25
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '0'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:15:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:16:23
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:16:26
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered empty.	Jagruti Patel (b) (4)	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:50:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 20:35:30

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Polymenorrhoea, LLT: Menstruation frequent - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 09:57:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:40
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 16:45:44
User entered 'frequent menstruation'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:42
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:44
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
User entered 'No (N)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:46
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:48
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '8 Nov 2020'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:49
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
User entered empty.	System	15 Apr 2021 16:45:02

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:51
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '27 Dec 2020'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:55
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
User entered empty.	System	15 Apr 2021 16:45:02

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:57
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:12:59
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:00
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:02
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:04
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:05
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:07
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:09
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:10
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:12
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:14
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:15
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:18
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'Related (RELATED)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:20
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:41
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:42
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'l'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:44
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:45
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:47
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:48
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
DataPoint Verified.	(b) (4), (b) (6)	17 Apr 2021 00:13:50
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:15:02
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	15 Apr 2021 16:45:02
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
User entered '0'	System	15 Apr 2021 16:45:02

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28
User entered '0'	System	15 Apr 2021 16:45:02

US3212326

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:50:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:17:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:50:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:37
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:00:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:16:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 04:58:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 04:58:43
Data point term sent to Coder	System	30 Aug 2020 21:17:12
User entered 'Levothyroxine (Synthroid)'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:17
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:19
User entered 'Hypothyroidism'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:22
User entered '75'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:24
User entered 'ug (ug)'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:25
User entered empty.	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:01:27
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:01:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:02:03
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:02:07
User entered empty.	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:02:12
User entered 'Un Jun 2006'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:02:17
User entered '0'	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:02:19
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:02:23
User entered empty.	Afifah Ayub (b) (4)	30 Aug 2020 21:16:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:02:28
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Aug 2020 21:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Aug 2020 21:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Aug 2020 21:16:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:02:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:26:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:26:03
Data point term sent to Coder	System	02 Nov 2020 14:14:43
Coding entries removed.	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:14:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:11:45
Data point term sent to Coder	System	28 Sep 2020 17:10:43
User entered 'Acetaminophen'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:11
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:26:11
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 19:26:09
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'not necessary per protocol ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	22 Dec 2020 22:28:13
Query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN did not meet the AE reporting criteria.' answered with 'SAR per protocol ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	22 Dec 2020 22:28:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[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. If the FEVER/PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:26:01
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:25:52
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:16:19
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:14:45
User entered 'fever/pain reactogenicity' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:14:38
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:26:55
User entered 'Fever (Solicited AR)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:17
User entered '325'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:20
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:24
User entered 'as needed (PRN)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:26
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:28
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:50:41
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:03:32
	(b) (4), (b) (6)	
User entered '25 Sep 2020' reason for change: Per	Heather Leary (b) (4)	28 Sep 2020 19:08:58
Query Resolution	(b) (4)	
User entered '27 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 17:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:33
User entered '0'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:03:36
User entered 'No (N)' reason for change: Per Query Resolution	Heather Leary (b) (4)	28 Sep 2020 19:08:58
User entered 'Yes (Y)'	(b) (4)	
	Afifah Ayub (b) (4)	28 Sep 2020 17:10:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:40
User entered '26 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	02 Nov 2020 14:14:27
User entered '27 Sep 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	28 Sep 2020 19:08:58
User entered empty.	Afifah Ayub (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:44
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	28 Sep 2020 17:10:28

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: FORMOTEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 06:31:05
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 06:31:05
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:55
Data point term sent to Coder	System	20 Nov 2020 20:47:23
Coding entries removed.	Reagan Reed (b) (4)	20 Nov 2020 20:47:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: FORMOTEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Oct 2020 11:13:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 11:13:23
Data point term sent to Coder	System	30 Oct 2020 17:47:51
User entered 'formeterol'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:03:58
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:04:01
User entered 'Autonomic Dysfunction' reason for change: Data Entry Error	Reagan Reed (b) (4)	20 Nov 2020 20:47:18
User entered 'shortness of breath'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:25:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
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) (4), (b) (6)	28 Dec 2020 19:26:27
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).	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:10:10
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:09:40
User entered '20' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:09:40
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)	22 Dec 2020 23:00:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:06
User entered '0.2'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:25:49
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:26:28
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:10:14
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:09:40
User entered 'ug (ug)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 15:09:40
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:00:17
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:07
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:15
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:17
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:21
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:25
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:26
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:29
User entered '21 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:32
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:35
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:48:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 17:48:08
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:48:08
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:47:45
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:38
User entered '21 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:48:08
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:04:46
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 17:47:45
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:13
User entered empty.	System	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:25:23
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN+CLAVULANIC ACID [AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 20:43:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 20:43:52
Data point term sent to Coder	System	15 Jan 2021 19:47:40
Coding entries removed.	Heather Leary (b) (4)	15 Jan 2021 19:47:09
DataPoint Un-verified.	(b) (4)	15 Jan 2021 19:47:09
Coding entries removed.	Heather Leary (b) (4)	15 Jan 2021 19:47:09
User entered 'AMOXICILLIN/clavulanate' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 19:47:09
User closed query 'Per source, Subject also took Meclizine. Please verify and update log accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:50:59
Query 'Per source, Subject also took Meclizine. Please verify and update log accordingly.' answered with 'correct' (Site from CRA).	Anna Pena (b) (4)	23 Nov 2020 14:57:23
User opened query 'Per source, Subject also took Meclizine. Please verify and update log accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:44:32
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:56

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:50:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:50:54
Data point term sent to Coder	System	30 Oct 2020 17:49:57
User entered 'Amoxicillin'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:04:58
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:25:20
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Un-verified.	(b) (4) Heather Leary (b) (4)	15 Jan 2021 19:47:09
User entered 'acute non-recurrent pansinusitis' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4)	15 Jan 2021 19:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:12
User entered 'sinus infection'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:14
User entered '500'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:18
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:20
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:05:24
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Oct 2020 17:49:15
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:25
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:27
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:29
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:05:33
User entered '25 Oct 2020'	Laura Ngansop Djampou	30 Oct 2020 17:49:15
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:34
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:37
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:05:40
User entered '30 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	20 Nov 2020 21:05:45
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 17:49:15
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User entered '2'	System	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User entered '1'	System	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:14
User entered '804 (804)'	System	30 Oct 2020 17:49:15

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 08:20:34
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 08:20:34
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:14
Data point term sent to Coder	System	23 Nov 2020 14:48:22
User entered 'Meclizine'	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:16
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	23 Nov 2020 22:51:19
User entered 'Autonomic Dysfunction'	(b) (4), (b) (6)	23 Nov 2020 14:48:05
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	23 Nov 2020 22:51:21
User entered '25'	Laura Ngansop Djampou	23 Nov 2020 14:48:05
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:24
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:26
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	23 Nov 2020 22:51:28
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Nov 2020 14:48:05
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:30
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:32
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:34
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:24:55
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Un-verified.	(b) (4)	
	Laura Ngansop Djampou	10 Dec 2020 19:59:45
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 19:59:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:36
User entered '3 Nov 2020'	Laura Ngansop Djampou	23 Nov 2020 14:48:05
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 22:51:39
User entered '0'	Laura Ngansop Djampou	23 Nov 2020 14:48:05
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	23 Nov 2020 22:51:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 14:48:05
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:24:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Un-verified.	(b) (4)	
	Laura Ngansop Djampou	10 Dec 2020 19:59:45
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 19:59:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:43
User entered '3 Nov 2020'	Laura Ngansop Djampou	23 Nov 2020 14:48:05
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	23 Nov 2020 22:51:45
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 14:48:05
	Laura Ngansop Djampou	
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User entered empty.	System	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User entered empty.	System	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:20:15
User entered empty.	System	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:26:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX WITH VITAMIN C, PRODUCT: ASCORBIC ACID;FOLIC ACID;VITAMIN B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:39:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:39:18
Data point term sent to Coder	System	25 Nov 2020 14:45:33
User entered 'B complex- Vitamin C-Folic Acid (folbee plus)'	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:26:15
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:28:50
Query 'Per source, Indication for Con Med only lists, "General Health". Please verify with source and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:28:49
User opened query 'Per source, Indication for Con Med only lists, "General Health". Please verify with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:26:45
User entered 'deficiency; general health'	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:27:10
User entered '5'	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:12
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:18
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:20
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:22
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:27:24
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:27:28
User entered 'UN Jan 2020'	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:27:30
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 14:44:39
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:27:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 14:44:39

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:27:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CARBONATE/VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:42:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:42:12
Data point term sent to Coder	System	25 Nov 2020 14:47:38
User entered 'Calcium Carbonate - Vitamin D3'	Afifah Ayub (b) (4)	25 Nov 2020 14:47:01
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:28:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:28:45
User entered 'deficiency; general health'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:29:19
User entered '500 / 200'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:24:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query 'Per DM CLR: Previous response indicate data was updated; however, the unit does not still correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4)	03 Feb 2021 11:26:16
Query 'Per DM CLR: Previous response indicate data was updated; however, the unit does not still correspond to the given dose of this medication. Review and update as applicable. ' answered with '500mg of calcium carbonate and 200mg of vitamin D3. units are correct ' (Site from DM).	Reagan Reed (b) (4)	02 Feb 2021 17:08:05
User opened query 'Per DM CLR: Previous response indicate data was updated; however, the unit does not still correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4)	28 Jan 2021 17:18:13
User closed query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit, kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 21:07:07
Query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit, kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 21:09:28
DataPoint Un-verified.	Reagan Reed (b) (4)	09 Dec 2020 21:09:22
User entered 'mg (mg)' reason for change: Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 21:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 16:29:23
User opened query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit, kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 11:40:15

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EAB) (1725)

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US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:24:33
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query 'Please specify dosing unit or list it as Unknown.' (Site from CRA).	(b) (4)	31 Dec 2020 18:15:09
Query 'Please specify dosing unit or list it as Unknown.' answered with 'resolved' (Site from CRA).	Reagan Reed (b) (4)	09 Dec 2020 21:09:33
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	09 Dec 2020 21:09:22
User opened query 'Please specify dosing unit or list it as Unknown.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 16:32:31
User entered 'n/a'	Afifah Ayub (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:34
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:32:36
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:47:01
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:37
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:40
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:32:42
User entered 'UN Jan 2020'	Afifah Ayub (b) (4)	25 Nov 2020 14:47:01
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:32:44
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 14:47:01
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:53
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:32:56
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 14:47:01

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:09
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL;ZEAXANTHIN, PRODUCTSYNONYM: LUTEIN-ZEAXANTHIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 14:49:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 14:49:08
Data point term sent to Coder	System	25 Nov 2020 14:48:40
User entered 'lutein-zeaxanthin'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:20
User entered 'eye health; general health'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:32
User entered '25 /5'	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:25
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:27
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:28
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:36
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:39
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:42
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:44
User entered 'Un UNK 2017'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:46
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:33:53
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:48:06
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:33:55
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 14:48:06

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:34:07
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 19:04:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 19:04:39
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 14:49:41
User entered 'fish oil'	Afifah Ayub (b) (4)	25 Nov 2020 14:49:07
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:09
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:12
User entered 'deficiency; general health'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:14
User entered '1200'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:34:16
User entered 'mg (mg)'	Afifah Ayub (b) (4)	25 Nov 2020 14:49:07
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:34:17
User entered empty.	Afifah Ayub (b) (4)	25 Nov 2020 14:49:07
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:23
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:34:26
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	25 Nov 2020 14:49:07
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:30
User entered 'Un UNK 2014'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 16:34:34
User entered '0'	Afifah Ayub (b) (4)	25 Nov 2020 14:49:07
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:36
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:34:40
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:50:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 14:49:07

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:50:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:26:46
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	11 Jan 2021 01:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	11 Jan 2021 01:39:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:06:02
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:42:03

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered '16 Dec 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:39:45

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:50:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Echocardiogram'	(b) (4) Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:39:45

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:18
User entered 'Other (OTHER)'	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:39:45
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:50:27

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty; reason for change Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:18
User entered 'Autonomic dysfunction'	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:39:45
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered '16 Dec 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:40:18

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:50:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Cardiac stress test'	(b) (4) Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:40:18

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:39
User entered 'Other (OTHER)'	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:40:18
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:50:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty; reason for change Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:39
	(b) (4)	
User entered 'Autonomic dysfunction'	Afifah Ayub (b) (4)	11 Jan 2021 01:40:18
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #1 ECHOCARDIOGRAM (16DEC2020). Verify and update start/end dates or remove duplicate entry as necessary.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:23:32
Query 'Per DM CLR: Please review start/end dates of Heather Leary this Procedure as it overlaps with Procedure #1 ECHOCARDIOGRAM (16DEC2020). Verify and update start/end dates or remove duplicate entry as necessary.	(b) (4)	23 Feb 2021 17:01:45
' answered with 'Subject began wearing holter monitor the same day as the echocardiogram was performed. This is correct.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review start/end dates of this Procedure as it overlaps with Procedure #1 ECHOCARDIOGRAM (16DEC2020). Verify and update start/end dates or remove duplicate entry as necessary.	(b) (4), (b) (6)	23 Feb 2021 09:20:10
' (Site from DM).		
User entered '16 Dec 2020'	Afifah Ayub (b) (4)	11 Jan 2021 01:40:52
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:50:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Holter monitor (ambulatory EKG)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:40:52

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:52
User entered 'Other (OTHER)'	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:40:52
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:50:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty; reason for change Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	11 Jan 2021 01:44:52
	(b) (4)	
User entered 'Autonomic dysfunction'	Afifah Ayub (b) (4)	11 Jan 2021 01:40:52
	(b) (4)	

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered '07 Dec 2020'	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:15

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:50:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Chest X-Ray'	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:15

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'Adverse Event (AE)'	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:15

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:50:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty.	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:15

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:50:27

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered '07 Dec 2020'	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:36

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:50:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered 'MRI Head'	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:36

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:50:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User closed query 'Per CDM: Please verify that Indication is provided as Adverse event. However no corresponding AE present in AE page. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 08:30:34
Query 'Per CDM: Please verify that Indication is provided as Adverse event. However no corresponding AE present in AE page. Please review and update accordingly. Else clarify.' answered with 'data entered is correct' (Site from DM).	Reagan Reed (b) (4) (b) (4)	25 Mar 2021 13:11:36
User opened query 'Per CDM: Please verify that Indication is provided as Adverse event. However no corresponding AE present in AE page. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:01:45
User entered 'Adverse Event (AE)'	Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:36

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:50:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:27:57
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:07:05
User entered empty.	(b) (4) Jagruti Patel (b) (4) (b) (4)	22 Mar 2021 14:29:36

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-MRNA-1273-P301000011'		

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 17:01:02
	System	

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Vicki'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Vicki'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Miller'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Miller'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'US'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 14:26:48
User entered '3'	System	24 Mar 2021 12:56:35
User entered '2'	System	25 Nov 2020 12:33:09
User entered '1'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-MRNA-1273-P301000011'		

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 17:01:02
	System	

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Vicki'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Vicki'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Miller'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Miller'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'US'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 14:26:48
User entered '3'	System	24 Mar 2021 12:56:35
User entered '2'	System	25 Nov 2020 12:33:09
User entered '1'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:50:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:42
User entered '21/Nov/2020 17:02'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:50:27

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)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-MRNA-1273-P301000011'		

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Vicki'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Vicki'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Miller'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Miller'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'US'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 14:26:48
User entered '3'	System	24 Mar 2021 12:56:35
User entered '2'	System	25 Nov 2020 12:33:09
User entered '1'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:50:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:42
User entered '25/Nov/2020 12:33'	System	25 Nov 2020 12:33:09

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:50:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 12:33:09

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-MRNA-1273-P301000011'		

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Vicki'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Vicki'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Miller'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Miller'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'US'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 14:26:48
User entered '3'	System	24 Mar 2021 12:56:35
User entered '2'	System	25 Nov 2020 12:33:09
User entered '1'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:50:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:33:00
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered '24/Mar/2021 05:56'	(b) (4) System	24 Mar 2021 12:56:35

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:50:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:33:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:56:35

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered	System	21 Nov 2020 17:01:02
'USA-US115-2020-MRNA-1273-P301000011'		

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'No (N)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Yes (Y)'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Vicki'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Vicki'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:43
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
Un-reviewed for Safety.	System	06 Apr 2021 14:26:48
Signature has been broken.	System	06 Apr 2021 14:26:48
User entered 'Miller'	System	06 Apr 2021 14:26:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:26:30
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
Un-reviewed for Safety.	System	24 Mar 2021 12:56:35
DataPoint Un-verified.	System	24 Mar 2021 12:56:35
User entered empty.	System	24 Mar 2021 12:56:35
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'Miller'	System	21 Nov 2020 17:01:02

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	04 Apr 2021 18:09:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 19:32:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 12:32:59
User entered 'US'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:50:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 14:26:48
User entered '3'	System	24 Mar 2021 12:56:35
User entered '2'	System	25 Nov 2020 12:33:09
User entered '1'	System	21 Nov 2020 17:02:52

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:50:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
User entered '06/Apr/2021 10:26'	System	06 Apr 2021 14:26:48

US3212326

Folder: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:50:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:32:51
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:54
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:28:13
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:26:48