

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

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:48:59

All time stamps listed in this document are displayed in GMT

US3212326

Form: Participant Creation

Generated On: 26 Nov 2020 10:48:59

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:48:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN UNK 2005
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

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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

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

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Collection date (<i>dd MMM yyyy</i>)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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)

Generated On: 26 Nov 2020 10:48:59

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)	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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 10:48:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	25 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 ☒

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

2 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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

9 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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 61
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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 68
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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 75
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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 82
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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

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

Patient Cloud Open Date & Time	05 DEC 2020 00:01
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Patient Cloud Close Date & Time	09 DEC 2020 23:59
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US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 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: 26 Nov 2020 10:48:59

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 10:48:59

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

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 10:48:59

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 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 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: 26 Nov 2020 10:48:59

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 10:48:59

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

Date and time of submission	
Patient Cloud Open Date & Time	20 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 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: 26 Nov 2020 10:48:59

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 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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 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: 26 Nov 2020 10:48:59

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 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: 26 Nov 2020 10:48:59

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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="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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

[Patient Cloud Open Date & Time](#)

04 SEP 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 579

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

[Patient Cloud Open Date & Time](#)

21 MAY 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: 26 Nov 2020 10:48:59

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

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

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 10:48:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

[Patient Cloud Open Date & Time](#)

03 SEP 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 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: 26 Nov 2020 10:48:59

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="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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:48:59

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 <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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:48:59

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

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

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

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3212326

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212326

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:48:59

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	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 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

	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 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	335 of 1928	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Taste	None	<input checked="" 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

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"/>
Day 33	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	339 of 1928	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:48:59

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"/>
Day 33	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:48:59

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	343 of 1928	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:48:59

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:48:59

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"/>
Day 33	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:48:59

	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"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	347 of 1928	

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:48:59

	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"/>
Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:48:59

	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"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

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"/>
Day 33	<input type="checkbox"/>

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	351 of 1928	

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input checked="" 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: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:48:59

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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	SICKD28
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US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

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Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:48:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

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)

2 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

369 of 1928

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

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

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

AEID	
Adverse event	POST-NASAL DRIP
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

<hr/>		COST OF THIS WORK UP. I ENCOURAGED HER TO GET FURTHER EVALUATION WITH THE CARDIOLOGIST/ HOLTER MONITORING AND POSSIBLY NEUROLOGY.
<hr/>		
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)		
<hr/>		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:48:59

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

Yes ☒

No ☐

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

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:59

Name of Medication	LEVOTHYROXINE (SYNTHROID)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPOTHYROIDISM
Dose per administration	75
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:59

	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"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:59

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	FEVER/PAIN REACTOGENICITY
Dose per administration	325
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:59

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
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 (3)

Generated On: 26 Nov 2020 10:48:59

Name of Medication	FORMETEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AUTONOMIC DYSFUNCTION
Dose per administration	0.2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:48:59

Name of Medication	AMOXICILLIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SINUS INFECTION
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:48:59

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		25 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>
<hr/>		
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"/>

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:48:59

Name of Medication	MECLIZINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AUTONOMIC DYSFUNCTION
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:48:59

	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)		3 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)		3 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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:48:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:48:59

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:48:59

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

Generated On: 26 Nov 2020 10:48:59

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)	1

US3212326

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:48:59

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)	1
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

Audit

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

US3212326

Form: Participant Creation

Generated On: 26 Nov 2020 10:48:59

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3212326'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	27 Aug 2020 21:14:19

US3212326

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:00
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:14:20

US3212326

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:18:53

US3212326

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Aug 2020 21:18:53

US3212326

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:17:39
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:14:21

US3212326

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:59

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Aug 2020 21:19:11

US3212326

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '46'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:48:59

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Enrollment

Generated On: 26 Nov 2020 10:48:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2020'	System	27 Aug 2020 21:19:23

US3212326

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:48:59

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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: 26 Nov 2020 10:48:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 21:19:27

US3212326

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Condition](#)

Audit	User	Time (GMT)
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.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	30 Aug 2020 21:16:36
User entered 'Hypothyroidism'	System	30 Aug 2020 21:15:09
	Afifah Ayub (b) (4)	30 Aug 2020 21:15:08
	(b) (4)	

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2006'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2006'	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	System	30 Aug 2020 21:15:08

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:48:59

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2006'	System	30 Aug 2020 21:15:20

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2006'	System	30 Aug 2020 21:15:34

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2005'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:31
User entered 'Un UNK 2005'	Afifah Ayub (b) (4) (b) (4)	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '2005'	System	30 Aug 2020 21:15:50

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 15:36'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:37:21
User entered 'Other (Other)'	Afifah Ayub (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:26:56
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:37:21
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 21:19:58

US3212326

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:27:16
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:20:43

US3212326

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:48:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If No, what is the reason?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:59

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:31

US3212326

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:48:59

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	27 Aug 2020 21:22:31

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	27 Aug 2020 21:22:52

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	27 Aug 2020 21:24:38

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '109274'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	27 Aug 2020 21:24:38

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	27 Aug 2020 21:24:38

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:23:22

US3212326

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:48:59

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Sep 2020 17:10:53
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 10:48:59

Height

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Height

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 (1)

Generated On: 26 Nov 2020 10:48:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	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: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 (1)

Generated On: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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 (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 15:36'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:48:59

Height

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:33:35
User entered '97.3' F	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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 (2)

Generated On: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 (2)

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3212326

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Aug 2020 21:18:01

US3212326

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '27 Aug 2020 17:11'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 22:13:07

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:34:03
User entered '27 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	27 Aug 2020 21:41:36

US3212326

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 21:41:49

US3212326

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 21:41:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '98.1'	System	28 Aug 2020 01:51:25

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Aug 2020 17:22:53
User entered '98.4'	System	28 Aug 2020 17:22:53

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	31 Aug 2020 16:58:55
User entered '98.3'	System	31 Aug 2020 16:58:55

US3212326

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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)
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' User entered '2'	System	28 Aug 2020 17:23:54

US3212326

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 17:24:24
User entered '28 Aug 2020 12:31'	System	28 Aug 2020 17:24:24

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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' User entered '01 Sep 2020 13:39'	System	01 Sep 2020 18:32:45
	System	01 Sep 2020 18:32:45

US3212326

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	10 Nov 2020 17:41:22
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	10 Nov 2020 17:41:22
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:08:29
User entered '3 Sep 2020'	Laura Ngansop Djampou (b) (4)	04 Sep 2020 14:51:04

US3212326

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 14:51:09

US3212326

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 15:46:35

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:09:46
User entered '17 Sep 2020'	Laura Ngansop Djampou	18 Sep 2020 19:15:43
	(b) (4)	

US3212326

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 19:15:49

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:18:20
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou	25 Sep 2020 20:22:12
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	25 Sep 2020 20:22:12

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	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: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered empty.	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: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '15'	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: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 20:23:07

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered empty.	Laura Ngansop Djampou	25 Sep 2020 20:23:48
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:19:00
User entered '14'	Laura Ngansop Djampou	25 Sep 2020 20:23:48
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 20:23:48

US3212326

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:48:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 16:28:39

US3212326

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:02
User entered '25 Sep 2020'	Laura Ngansop Djampou	25 Sep 2020 20:24:55
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:48:59

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered 'Yes (Y)'	Laura Ngansop Djampou	25 Sep 2020 20:24:55
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered '10:36'	Laura Ngansop Djampou	25 Sep 2020 20:24:55
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:22:33
User entered 'No (N)'	Laura Ngansop Djampou	25 Sep 2020 20:24:55
	(b) (4)	

US3212326

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 20:24:55

US3212326

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:25:01

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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.' (Site from System). 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'	Heather Leary (b) (4)	28 Sep 2020 19:09:12
User entered '1'	System	25 Sep 2020 23:56:19

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:48:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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.' (Site from System).	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'	System	26 Sep 2020 17:10:31
User entered '1'	System	26 Sep 2020 17:10:31

US3212326

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:48:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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)
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' User entered '4'	System	26 Sep 2020 17:10:59

US3212326

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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-fbdc947663a'	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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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-fbdc947663a'	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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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-fbdc947663a'	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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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-fbdc947663a'	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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 21:41:47
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 21:41:47

US3212326

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 21:48:32

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:22
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	14 Oct 2020 14:23:01

US3212326

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 14:23:07

US3212326

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 16:39:26

US3212326

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	30 Oct 2020 17:44:54

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:01
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 17:45:35
	(b) (4)	

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 17:45:35

US3212326

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:13:23
User entered 'Yes (Y)'	Laura Ngansop Djampou	30 Oct 2020 17:46:02
	(b) (4)	

US3212326

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 17:46:02

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[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: '2020-10-29T13:12:53', 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: 26 Nov 2020 10:48:59

[Have you been exposed to someone with 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: '2020-10-29T13:12:58', 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: 26 Nov 2020 10:48:59

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[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: '2020-11-03T10:09:52', 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: 26 Nov 2020 10:48:59

Have you been exposed to someone with 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: '2020-11-03T10:09:56', 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: 26 Nov 2020 10:48:59

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[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: '2020-11-10T10:45:46', 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: 26 Nov 2020 10:48:59

[Have you been exposed to someone with 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: '2020-11-10T10:45:50', 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: 26 Nov 2020 10:48:59

[Date and time of submission](#)

Audit	User	Time (GMT)
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'	System	10 Nov 2020 16:37:51
User entered '10 Nov 2020 10:45:52'	System	10 Nov 2020 16:37:51

US3212326

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

[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 Oct 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: 26 Nov 2020 10:48:59

[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 Oct 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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

[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 Oct 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: 26 Nov 2020 10:48:59

[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 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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

[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 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: 26 Nov 2020 10:48:59

[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 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: 26 Nov 2020 10:48:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:03
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:31:03

US3212326

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:48:59

[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 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: 26 Nov 2020 10:48:59

[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 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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Have you been exposed to someone with 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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 14:40:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:48:59

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	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: 26 Nov 2020 10:48:59

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '15:33'	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: 26 Nov 2020 10:48:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	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: 26 Nov 2020 10:48:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	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: 26 Nov 2020 10:48:59

[Date](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	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: 26 Nov 2020 10:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered '99'	Afifah Ayub (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered '98.6' F	Afifah Ayub (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:48:59

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	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: 26 Nov 2020 10:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 10:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:54:35

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31
User entered 'Day 2 (Day 2)'	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: 26 Nov 2020 10:48:59

[Date](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	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: 26 Nov 2020 10:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	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: 26 Nov 2020 10:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Oct 2020 15:16:40

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:48:59

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F	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: 26 Nov 2020 10:48:59

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 10:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 10:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	27 Oct 2020 15:31:31
User entered 'Day 3 (Day 3)'	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: 26 Nov 2020 10:48:59

[Date](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	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: 26 Nov 2020 10:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	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: 26 Nov 2020 10:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Oct 2020 14:34:13

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:48:59

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	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: 26 Nov 2020 10:48:59

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 10:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 10:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	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: 26 Nov 2020 10:48:59

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	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: 26 Nov 2020 10:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	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: 26 Nov 2020 10:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:48:59

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	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: 26 Nov 2020 10:48:59

[Date](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	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: 26 Nov 2020 10:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered '1'	(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: 26 Nov 2020 10:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	03 Nov 2020 21:37:01
User entered empty.	System	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 21:37:01
User entered empty.	Afifah Ayub (b) (4)	27 Oct 2020 15:31:31

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:48:59

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	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: 26 Nov 2020 10:48:59

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:48:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(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
Query 'Data is required. Please complete.' answered with 'will update later.' (Site from System).	(b) (4)	
	Afifah Ayub (b) (4)	21 Oct 2020 15:54:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	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: 26 Nov 2020 10:48:59

[Date of Test](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	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: 26 Nov 2020 10:48:59

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Afifah Ayub Swab)'	(b) (4)	21 Oct 2020 15:54:52

US3212326

Folder: Covid-19 Assessment 20 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:48:59

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:48:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:03

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:39:56
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	26 Oct 2020 16:39:56
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	23 Oct 2020 14:35:23
	(b) (4)	

US3212326

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Oct 2020 14:35:23

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	21 Oct 2020 15:55:22

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '14:37'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Height (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:48:59

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '16'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 15:55:53

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:00

US3212326

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	21 Oct 2020 15:56:06

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:10

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:15

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[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: 26 Nov 2020 10:48:59

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:18

US3212326

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:48:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	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: 26 Nov 2020 10:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 16:40:27

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:48:59

[Visit Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Physical Exam](#)

Audit	User	Time (GMT)
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:48:59

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:48:59

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:48:59

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:58:20

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '10:10'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
User entered '15'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: **Unscheduled 18 Nov 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:48:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: **Unscheduled 18 Nov 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:48:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:48:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 18:59:50

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:58

US3212326

Folder: Unscheduled 18 Nov 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:48:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 18:59:58

US3212326

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:48:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:57:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou	30 Oct 2020 17:49:33
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	27 Aug 2020 21:23:31
	(b) (4)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	23 Nov 2020 15:29:56
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
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
Coding entries removed.	(b) (4)	
	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) (b) (4)	21 Nov 2020 12:48:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:48:59
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) (b) (4)	30 Oct 2020 18:03:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 18:03:55
Data point term sent to Coder	System	30 Oct 2020 18:02:24
User entered 'Sinus Infection'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:08
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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 (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:53:19
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:42
User entered '23 Oct 2020'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:44
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
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)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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.	(b) (4)	
	Reagan Reed (b) (4)	23 Nov 2020 14:36:14
User entered '2 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	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) (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
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

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:48
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Severity](#)

Audit	User	Time (GMT)
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)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:52
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Death](#)

Audit	User	Time (GMT)
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)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Life threatening](#)

Audit	User	Time (GMT)
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 (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:29
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:35
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:38
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:56:40
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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) (b) (4)	18 Nov 2020 15:44:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:43:54
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 (b) (4)	30 Oct 2020 18:01:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

Action taken with investigational product

Audit	User	Time (GMT)
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
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	20 Nov 2020 21:02:02
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 (b) (4)	30 Oct 2020 18:01:59

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Folder: Adverse Events

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Generated On: 26 Nov 2020 10:48:59

[None](#)

Audit	User	Time (GMT)
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
User entered '1'	Laura Ngansop Djampou	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
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
User entered '0'	Laura Ngansop Djampou	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:36
User entered '0'	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Outcome](#)

Audit	User	Time (GMT)
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

US3212326

Folder: Adverse Events

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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)	20 Nov 2020 20:57:41
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Narrative](#)

Audit	User	Time (GMT)
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)	

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:48:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 18:01:59

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:57:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: 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) (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) (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) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:02
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:41
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:15
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:04
User entered '25 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:20
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:23
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:27
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:36
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:40
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:41
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:58:43
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:06
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:48:46
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:18
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:21
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
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

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:25
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Outcome](#)

Audit	User	Time (GMT)
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) (b) (4)	19 Nov 2020 14:52:27

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:29
User entered empty.	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: 26 Nov 2020 10:48:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:48:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 14:52:27

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:08
User entered 'USA-US115-2020-mRNA-1273-P301000011'	System	21 Nov 2020 17:01:02
User entered 'New'	(b) (4), (b) (6)	21 Nov 2020 17:01:02

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Adverse event](#)

Audit	User	Time (GMT)
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

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:26
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:49:03
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:41
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:51
User entered '18 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:55
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:28:59
User entered empty.	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) System	24 Nov 2020 20:18:26 19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Severity](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:04
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:55
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:56
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:59
User entered '0'	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: 26 Nov 2020 10:48:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:30:01
User entered empty.	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: 26 Nov 2020 10:48:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:30:03
User entered empty.	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: 26 Nov 2020 10:48:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:01
User entered empty.	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: 26 Nov 2020 10:48:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:03
User entered empty.	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: 26 Nov 2020 10:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:08
User entered '0'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:09
User entered '0'	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: 26 Nov 2020 10:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:20
User entered '1'	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: 26 Nov 2020 10:48:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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)

Generated On: 26 Nov 2020 10:48:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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 21:42:34
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:42:32
Query 'Per Progress note in source, AE is 'not related' to study procedure. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Reagan Reed (b) (4)	24 Nov 2020 14:50:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	24 Nov 2020 14:50:23
User opened 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)	23 Nov 2020 22:50:10
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)

Generated On: 26 Nov 2020 10:48:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 21:40:37
User entered empty.	System	19 Nov 2020 21:40:37
	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: 26 Nov 2020 10:48:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:33:06
User entered '0'	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: 26 Nov 2020 10:48:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:33:12
User entered '1'	Afifah Ayub (b) (4) (b) (4)	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:19
User entered '0'	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: 26 Nov 2020 10:48:59

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	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) (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) (b) (4)	19 Nov 2020 21:40:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:36:26
User entered empty.	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: 26 Nov 2020 10:48:59

[Narrative](#)

Audit	User	Time (GMT)
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

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[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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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 21:40:37

US3212326

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:48:59

[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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:48:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (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) (b) (4)	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:19
User entered 'Hypothyroidism'	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: 26 Nov 2020 10:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:22
User entered '75'	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: 26 Nov 2020 10:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:24
User entered 'ug (ug)'	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: 26 Nov 2020 10:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:25
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: 26 Nov 2020 10:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:27
User entered 'once daily (QD)'	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: 26 Nov 2020 10:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:03
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:07
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: 26 Nov 2020 10:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:12
User entered 'Un Jun 2006'	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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:17
User entered '0'	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: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:23
User entered empty.	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: 26 Nov 2020 10:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Aug 2020 21:16:31

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(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)	04 Nov 2020 01:26:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 01:26:03
Data point term sent to Coder Coding entries removed.	System	02 Nov 2020 14:14:43
	Afifah Ayub (b) (4)	02 Nov 2020 14:14:38
	(b) (4)	
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)	28 Sep 2020 17:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	28 Sep 2020 17:11:45
Data point term sent to Coder User entered 'Acetaminophen'	System	28 Sep 2020 17:10:43
	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: 26 Nov 2020 10:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Indication](#)

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:32
User entered '25 Sep 2020' reason for change: Per Query Resolution	Heather Leary (b) (4)	28 Sep 2020 19:08:58
User entered '27 Sep 2020'	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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)'	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: 26 Nov 2020 10:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

Name of Medication

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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) (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.	Coder Import (b) (4) (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) (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: 26 Nov 2020 10:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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: 26 Nov 2020 10:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:15
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 17:47:45
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:21
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 17:47:45
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:26
User entered empty.	Laura Ngansop Djampou	30 Oct 2020 17:47:45
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:29
User entered '21 Oct 2020'	Laura Ngansop Djampou	30 Oct 2020 17:47:45
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	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	30 Oct 2020 17:47:45

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:38
User entered '21 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	30 Oct 2020 17:48:08
User entered empty.	(b) (4)	
	Laura Ngansop Djampou	30 Oct 2020 17:47:45
	(b) (4)	

US3212326

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:46
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: 26 Nov 2020 10:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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
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) (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) (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: 26 Nov 2020 10:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:58
User entered 'No (N)'	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: 26 Nov 2020 10:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:12
User entered 'sinus infection'	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: 26 Nov 2020 10:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:20
User entered empty.	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: 26 Nov 2020 10:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:24
User entered 'twice daily (BID)'	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: 26 Nov 2020 10:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:25
User entered empty.	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: 26 Nov 2020 10:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:27
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:29
User entered empty.	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: 26 Nov 2020 10:48:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:33
User entered '25 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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:37
User entered 'No (N)'	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: 26 Nov 2020 10:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:40
User entered '30 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: 26 Nov 2020 10:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:05:45
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: 26 Nov 2020 10:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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: 26 Nov 2020 10:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:16
User entered 'No (N)'	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: 26 Nov 2020 10:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:19
User entered 'Autonomic Dysfunction'	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: 26 Nov 2020 10:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:21
User entered '25'	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: 26 Nov 2020 10:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:28
User entered 'once (ONCE)'	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: 26 Nov 2020 10:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:30
User entered empty.	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: 26 Nov 2020 10:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:32
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:34
User entered empty.	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: 26 Nov 2020 10:48:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:36
User entered '3 Nov 2020'	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: 26 Nov 2020 10:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:39
User entered '0'	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: 26 Nov 2020 10:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:41
User entered 'No (N)'	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: 26 Nov 2020 10:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:43
User entered '3 Nov 2020'	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: 26 Nov 2020 10:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:45
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: 26 Nov 2020 10:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:48:05

US3212326

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:48:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: SAE USA-US115-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 10:48:59

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'USA-US115-2020-MRNA-1273-P301000011'	System	21 Nov 2020 17:01:02

US3212326

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:48:59

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 17:02:52

US3212326

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:48:59

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 17:02:19
User entered 'USA-US115-2020-MRNA-1273-P301000011'	System	21 Nov 2020 17:01:02

US3212326

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

Form: Safety Report Form

Generated On: 26 Nov 2020 10:48:59

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 17:02:52

US3212326

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:48:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:48:59

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 entered 'I'	(b) (4), (b) (6)	21 Nov 2020 17:02:52