US3212066 (Prod: DM Clinical Research - ERN - PPDS)

All time stamps listed in this document are displayed in GMT

US3212066

Form: Participant Creation

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Participant ID	US3212066

mRNA-1273-P301 Completion Guidelines

US3212066

Folder: Screening

Form: Visit Date

Data signed: ████████ (b) (4) ████████ **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 06 AUG 2020 |

| Was visit performed at the participant's home or at the clinic? | Home ○ |
| | Clinic ● |

| Folder OID | SCRN |

US3212066

Folder: Screening

Form: Demographics

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female ●
	Male ○
Ethnicity	Hispanic or Latino ○
	Not Hispanic or Latino ●
	Not Reported ○
	Unknown ○

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

Date of Informed Consent *(dd MMM yyyy)*	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version	Amendment 1 ●
	Amendment 2 ○
	Amendment 3 ○
	Amendment 4 ○
	Amendment 5 ○
Was participant enrolled in the study?	Yes ●
	No ○
If No, indicate reason for screen fail	Withdrew Consent ○
	Inclusion/Exclusion ○
	Cohort Full ○
	Other ○
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ○
	No ●
If Yes, previous participant number	
Enrollment Trigger	1

US3212066

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Did the participant meet all eligibility criteria?   Yes ●

No ◯

Were any significant conditions reported?   Yes ●
                                                             No ◯

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Condition	UTERINE ABLATION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3212066

Folder: Screening

Form: Medical History (4)

Data signed: ░░░░░ (b) (4) ░░░░░ **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3212066

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3212066

Folder: Screening

Form: Vital Signs

Data signed: [(b) (4)] **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	10:48 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:48
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	148.6 lb
BMI *(xxx.x)*	26.37835 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Screening

Form: Physical Examination

Data signed:　　　　(b) (4)　　　　**26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?	Yes ●
	No ◯

Date of examination *(dd MMM yyyy)* | 06 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*	06 AUG 2020

Is the participant of childbearing potential?   Yes ○

No ●

If No, what is the reason?   Surgically sterile ●

Post-menopausal ○

Partner medically sterile ○

Not reached age of Menarche ○

Other ○

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

US3212066

Folder: Screening

Form: Risk of Exposure

Data signed: ⬛⬛⬛ (b) (4) ⬛⬛⬛ 26 Mar 2021 18:03:51

Generated On: 11 Aug 2021 22:07:04

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	RESEARCH ADMINISTRATION

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: [b) (4)] **26 Mar 2021 18:03:51**

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PARTICIPANT GOES IN PERSON TO THEIR MAIN WORKPLACE MORE THAN 2 DAYS/WEEK. PARTICIPANT LIVES WITH CHILDREN IN THE HOUSEHOLD LIKELY TO GO BACK TO SCHOOL IN PERSON THIS YEAR...

US3212066

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: ░░░░░░░ (b) (4) ░░░░░░░ **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

What was the date of randomization? *(dd MMM yyyy)*	06 AUG 2020
What was the participant's randomization number?	101645

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes	◯
	No	⬤
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes	◯
	No	⬤
Severe obesity (body mass index > or = 40kg/m2)	Yes	◯
	No	⬤
Diabetes (Type I, Type 2, or gestational)	Yes	◯
	No	⬤
Liver Disease	Yes	◯
	No	⬤

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4)   **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Height	ND - Not Done
Weight	ND - Not Done

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	10:48 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:48
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: [(b) (4)] **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	12:58 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 12:58
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	51 mmHg
Diastolic Blood Pressure units	MMHG

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.

FDA-CBER-2022-1614-0615937

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
Participant declined due to Adverse Event	◯
Physician withheld dose due to Adverse Event	◯
Death	◯
Lost To Follow-Up	◯
Physician Decision	◯
Pregnancy	◯
Protocol Deviation	◯
Study Terminated by Sponsor	◯
Withdrawal of Consent by Participant	◯
Confirmed COVID-19	◯
Other	◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	06 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:23 (24 HR)
Treatment Date and Time (derived)	06 AUG 2020 12:23
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0615938

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	06 AUG 2020
Collection time *(00:00-23:59)*	11:51 (24 HR)
Collection date and time (derived)	06 AUG 2020 11:51

US3212066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*			06 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	06 AUG 2020 11:40
Nasopharyngeal Swab 2	No		

Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4)   **26 Mar 2021 18:04:00**
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.4 °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	06 AUG 2020 12:52
PC Open Date & Time	06 AUG 2020 12:43
PC Close Date & Time	06 AUG 2020 15:13

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	99.1 °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	06 AUG 2020 17:50
PC Open Date & Time	06 AUG 2020 16:08
PC Close Date & Time	07 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.2 °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	07 AUG 2020 12:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	08 AUG 2020 21:40
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:07:04

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**	98.3 °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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	09 AUG 2020 18:07
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	10 AUG 2020 18:05
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 AUG 2020 17:51
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0615948

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:07:04

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	12 AUG 2020 18:18
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:07:04

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	06 AUG 2020 12:52
PC Open Date & Time	06 AUG 2020 12:43
PC Close Date & Time	06 AUG 2020 15:13

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

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	06 AUG 2020 16:09
PC Open Date & Time	06 AUG 2020 16:08
PC Close Date & Time	07 AUG 2020 11:59

TIMEPOINT	DAY 2
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	07 AUG 2020 12:11
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	08 AUG 2020 21:40
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	09 AUG 2020 18:05
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	10 AUG 2020 18:04
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

TIMEPOINT	DAY 6

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	11 AUG 2020 17:51
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

TIMEPOINT	DAY 7
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	12 AUG 2020 18:17
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04

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 ○

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No	●
	Yes	○

PC Time stamp	06 AUG 2020 12:53
PC Open Date & Time	06 AUG 2020 12:43
PC Close Date & Time	06 AUG 2020 15:13

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE

None	●
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	●
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	06 AUG 2020 17:50
PC Open Date & Time	06 AUG 2020 16:08
PC Close Date & Time	07 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04

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 ●

	Yes ◯
PC Time stamp	07 AUG 2020 12:12
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:07:04

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 ⬤

Yes ◯

PC Time stamp	08 AUG 2020 21:41
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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 ⬤

FDA-CBER-2022-1614-0615966

Yes ◯

PC Time stamp	09 AUG 2020 18:06
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04

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 ⬤

	Yes ◯
PC Time stamp	10 AUG 2020 18:06
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04

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 ⬤

	Yes ◯
PC Time stamp	11 AUG 2020 17:52
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04

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 ●

	Yes ◯
PC Time stamp	12 AUG 2020 18:17
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ◯
	No interference with activity ⬤
	Some interference with activity ◯
	Significant; prevents daily activity ◯

PC Time Stamp	14 AUG 2020 06:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ⭕
	No interference with activity ⭕
	Some interference with activity ⚫
	Significant; prevents daily activity ⭕
PC Time Stamp	14 AUG 2020 12:09
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **FATIGUE**	None ⬭
	No interference with activity ⬛
	Some interference with activity ⬭
	Significant; prevents daily activity ⬭
PC Time Stamp	16 AUG 2020 07:04
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **FATIGUE**	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯

PC Time Stamp	16 AUG 2020 13:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 8
Select one response below to indicate the level of your **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 ◯
PC Time stamp	14 AUG 2020 06:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	14 AUG 2020 06:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	16 AUG 2020 07:04
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	16 AUG 2020 13:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

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   PARTICIPANT IS IN ILLNESS
                                               VISIT/CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4)　　**26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　1

US3212066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4)   **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

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   _____

US3212066

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: [(b) (4)] **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4)   **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 AUG 2020

Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: ▒▒▒▒▒ (b) (4) ▒▒▒▒▒ **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?　Yes ⬤

No ◯

Continuing Flag　1

US3212066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: [gray bar] (b) (4) [gray bar] **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	09:33 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 09:33
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ○
	Post-Dose ●
Were vital signs assessed?	Yes ○
	No ●
Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)* — 03 SEP 2020

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

Was study treatment given?

Yes ◯
No ⬤

If No, reason not given

Participant declined due to Adverse Event ◯
Physician withheld dose due to Adverse Event ◯
Death ◯
Lost To Follow-Up ◯
Physician Decision ◯
Pregnancy ◯
Protocol Deviation ◯
Study Terminated by Sponsor ◯
Withdrawal of Consent by Participant ◯
Confirmed COVID-19 ⬤
Other ◯

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

What was the study treatment? _____

What was the treatment date? *(dd MMM yyyy)* _____

What was the treatment time? *(00:00-23:59)* _____

Treatment Date and Time (derived) _____

Which arm was used to give treatment?

Left Arm ◯
Right Arm ◯

What was the frequency of the study treatment dosing? _____

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

FDA-CBER-2022-1614-0615992

| Was the sample collected? | Yes ● |
| | No ○ |

Collection date *(dd MMM yyyy)*	03 SEP 2020
Collection time *(00:00-23:59)*	10:49 (24 HR)
Collection date and time (derived)	03 SEP 2020 10:49

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*			03 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:44	03 SEP 2020 10:44
Nasopharyngeal Swab 2	No		

US3212066
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4)   **26 Mar 2021 18:04:00**
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: ████████ (b) (4) ████████ **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

| 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

US3212066

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4)   **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?   Yes ●

No ○

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

Please select one status for the follow-up contact   Contact Made ●

Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: ████████ (b) (4) ████████ **26 Mar 2021 18:03:50**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                    No ◯

Continuing Flag   1

Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4)   **26 Mar 2021 18:04:00**
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	08 OCT 2020
Time of assessment *(00:00-23:59)*	09:12 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 09:12
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212066

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed? Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)* 08 OCT 2020

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

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	08 OCT 2020
Collection time *(00:00-23:59)*	09:45 (24 HR)
Collection date and time (derived)	08 OCT 2020 09:45

US3212066

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: ‎ (b) (4) ‎ **26 Mar 2021 18:04:00**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

                                                                                                 No ◯

Continuing Flag   1

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 OCT 2020 11:44:00
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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	13 OCT 2020 16:53:46
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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	20 OCT 2020 04:52:52
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 17:28:07
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 04:52:58
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 18:29:41
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 18:06:36
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 11:03:20
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 10:02:18
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 05:15:09
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 06:43:50
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this 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	26 DEC 2020 09:23:45
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 08:31:53
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 07:08:50
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 07:14:07
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 10:45:07
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 06:29:55
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 05:44:49
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 08:08:52
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 16:50:12
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 05:35:21
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 08:44:47
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 08:42:45
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 21:30:58
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 08:36:06
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 08:33:21
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 08:37:29
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 08:35:31
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 20:30:05
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

Fever (Temperature ≥ 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 ○

FDA-CBER-2022-1614-0616040

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

FDA-CBER-2022-1614-0616048

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
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 ⃝

FDA-CBER-2022-1614-0616050

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 327**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0616052

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 334**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0616058

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature ≥ 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 ⭕

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

FDA-CBER-2022-1614-0616064

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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):

Symptom	
Fever (Temperature ≥ 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 ⭕

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ⚪

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 418**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

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):

Symptom	
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 ◯

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0616090

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	06 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 467**

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 474**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘
	Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘
	Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘
	Yes ⭘

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘
	Yes ⭘

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ⃝

FDA-CBER-2022-1614-0616096

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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 ⃝

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   **DAY 495**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0616100

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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):

Symptom	
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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   DAY 509

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

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

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

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

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

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

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

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 516**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Symptom	
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 ⚪

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ⭕

FDA-CBER-2022-1614-0616108

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   **DAY 530**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0616110

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616112

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616118

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ○

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616128

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

FDA-CBER-2022-1614-0616130

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

FDA-CBER-2022-1614-0616132

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 614**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝
	Yes ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616138

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Fever (Temperature ≥ 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 ⚪

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-0616152

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616154

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 698**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

FDA-CBER-2022-1614-0616158

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ◯

FDA-CBER-2022-1614-0616164

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT **DAY 733**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
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 ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 754**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT　　　　　　　　　　　　　　　　　　　DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT   DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 782**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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°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 ◯

FDA-CBER-2022-1614-0616184

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT	**DAY 796**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature $\geq$ 100.4°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 ⬭

FDA-CBER-2022-1614-0616186

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 05:35:07

US3212066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4)   **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: [(b) (4)] **26 Mar 2021 18:03:51**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 03 DEC 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

                                                                                                              No ○

Continuing Flag   1

US3212066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

| Was Contact Attempted? | Yes ● |
| | No ○ |

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

| Please select one status for the follow-up contact | Contact Made ○ |
| | Contact Not Made ● |

| Comments | CALLED FOR SAFETY CALL, NO ANSWER, LEFT VOICEMAIL |
| *If Contact Not Made, please provide Comments* | AND SENT TEXT. |

US3212066

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3212066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | VISIT4 |

US3212066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	12:41 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:41
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212066

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   26 FEB 2021

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

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	26 FEB 2021
Collection time *(00:00-23:59)*	13:32 (24 HR)
Collection date and time (derived)	26 FEB 2021 13:32

US3212066

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?　　　　　　　　　　　　　Yes ●

No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3212066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	31 MAR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3212066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: [(b) (4)] 30 Apr 2021 18:13:11

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 APR 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	CALLED SUBJECT REGARDING DAY 269 SAFETY CALL. NO
If Contact Not Made, please provide Comments	ANSWER, VOICEMAIL LEFT.

US3212066

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: [(b) (4)] **30 Apr 2021 18:13:11**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3212066
Folder: Safety Call Day 299 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

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

US3212066

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?　　　　　　　　　Yes ◯

No ◯

Continuing Flag

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Date of Contact	04 JAN 2021
Time of Contact	12:09
Date and Time of Contact (derived)	04 JAN 2021 12:09

Type of Contact	
Clinic Visit - Scheduled	◯
Clinical Visit - Unscheduled	⬤
Safety Call	◯
Convalescent Tele-visit	◯

Has the subject reported symptoms of SARS-COV-2?	
Yes	⬤
No	◯

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day   Day 1 ●
                                                         Day 2 ○
                                                         Day 3 ○
                                                         Day 4 ○
                                                         Day 5 ○
                                                         Day 6 ○
                                                         Day 7 ○
                                                         Day 8 ○
                                                         Day 9 ○
                                                         Day 10 ○
                                                         Day 11 ○
                                                         Day 12 ○
                                                         Day 13 ○
                                                         Day 14 ○
                                                         Day 15 ○
                                                         Day 16 ○
                                                         Day 17 ○
                                                         Day 18 ○
                                                         Day 19 ○
                                                         Day 20 ○
                                                         Day 21 ○
                                                         Day 22 ○
                                                         Day 23 ○
                                                         Day 24 ○
                                                         Day 25 ○
                                                         Day 26 ○
                                                         Day 27 ○
                                                         Day 28 ○
                                                         Day 29 ○
                                                         Day 30 ○
                                                         Day 31 ○
                                                         Day 32 ○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	24 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell   None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion	
	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯

Runny Nose (Rhinorrhea)	
	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Nausea	
	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Vomiting	
	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Diarrhea	
	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Sore Throat	
	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) **02 Apr 2021 18:02:50**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ⬤
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	25 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Runny Nose (Rhinorrhea)	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Nausea	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Vomiting	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Diarrhea	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Sore Throat	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ○
Day 2 ○
Day 3 ●
Day 4 ○
Day 5 ○
Day 6 ○
Day 7 ○
Day 8 ○
Day 9 ○
Day 10 ○
Day 11 ○
Day 12 ○
Day 13 ○
Day 14 ○
Day 15 ○
Day 16 ○
Day 17 ○
Day 18 ○
Day 19 ○
Day 20 ○
Day 21 ○
Day 22 ○
Day 23 ○
Day 24 ○
Day 25 ○
Day 26 ○
Day 27 ○
Day 28 ○
Day 29 ○
Day 30 ○
Day 31 ○
Day 32 ○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	26 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nasal Congestion

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ⬤
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ⭕
	Day 34 ⭕
	Day 35 ⭕
	Day 36 ⭕
	Day 37 ⭕
	Day 38 ⭕
	Day 39 ⭕
	Day 40 ⭕
Date	27 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Cough	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕

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Not Done ◯

Fatigue
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell
None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

FDA-CBER-2022-1614-0616223

Nasal Congestion

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

FDA-CBER-2022-1614-0616224

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ●
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	28 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ⬤
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	29 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ◯

Fatigue

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nasal Congestion

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Runny Nose (Rhinorrhea)

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Nausea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Vomiting

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Diarrhea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Sore Throat

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

US3212066

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ●
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	30 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Muscle Aches (Myalgia)
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Body Aches
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Headache
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Taste
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Smell
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Nasal Congestion

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Runny Nose (Rhinorrhea)

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Nausea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Vomiting

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Diarrhea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Sore Throat

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	⬭
Day 2	⬭
Day 3	⬭
Day 4	⬭
Day 5	⬭
Day 6	⬭
Day 7	⬭
Day 8	⬤
Day 9	⬭
Day 10	⬭
Day 11	⬭
Day 12	⬭
Day 13	⬭
Day 14	⬭
Day 15	⬭
Day 16	⬭
Day 17	⬭
Day 18	⬭
Day 19	⬭
Day 20	⬭
Day 21	⬭
Day 22	⬭
Day 23	⬭
Day 24	⬭
Day 25	⬭
Day 26	⬭
Day 27	⬭
Day 28	⬭
Day 29	⬭
Day 30	⬭
Day 31	⬭
Day 32	⬭

	Day 33 ⭕
	Day 34 ⭕
	Day 35 ⭕
	Day 36 ⭕
	Day 37 ⭕
	Day 38 ⭕
	Day 39 ⭕
	Day 40 ⭕
Date	31 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Cough	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⭕
	Mild ⭕
	Moderate ⭕
	Severe ⭕

Not Done ◯

Fatigue

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

FDA-CBER-2022-1614-0616239

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) **02 Apr 2021 18:02:50**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	⬤
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	01 JAN 2021
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Runny Nose (Rhinorrhea)

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Nausea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Vomiting

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Diarrhea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Sore Throat

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ⬤
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	02 JAN 2021
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	

Chills	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Muscle Aches (Myalgia)
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Body Aches
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Headache
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Taste
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

New Loss of Smell
- None ◯
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Nasal Congestion

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Runny Nose (Rhinorrhea)

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Nausea

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Vomiting

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Diarrhea

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Sore Throat

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Data signed: (b) (4) 02 Apr 2021 18:02:50
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	●
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	03 JAN 2021
Assessment Not Done	False
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia)

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell

None ○
Mild ○
Moderate ○
Severe ○
Not Done ○

Nasal Congestion

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Data signed: (b) (4) **02 Apr 2021 18:02:50**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	⬤
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	04 JAN 2021
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

Muscle Aches (Myalgia)   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

Body Aches   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

Headache   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

New Loss of Taste   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

New Loss of Smell   None ⬤
                                                          Mild ◯
                                                      Moderate ◯
                                                        Severe ◯
                                                      Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

FDA-CBER-2022-1614-0616256

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ⬤
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	05 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia) None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

FDA-CBER-2022-1614-0616259

Nasal Congestion

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

FDA-CBER-2022-1614-0616260

Symptom Day

Day 1	⬭
Day 2	⬭
Day 3	⬭
Day 4	⬭
Day 5	⬭
Day 6	⬭
Day 7	⬭
Day 8	⬭
Day 9	⬭
Day 10	⬭
Day 11	⬭
Day 12	⬭
Day 13	⬭
Day 14	⬤
Day 15	⬭
Day 16	⬭
Day 17	⬭
Day 18	⬭
Day 19	⬭
Day 20	⬭
Day 21	⬭
Day 22	⬭
Day 23	⬭
Day 24	⬭
Day 25	⬭
Day 26	⬭
Day 27	⬭
Day 28	⬭
Day 29	⬭
Day 30	⬭
Day 31	⬭
Day 32	⬭

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) **02 Apr 2021 18:02:50**

Generated On: 11 Aug 2021 22:07:04

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	06 JAN 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.4 F

Chills	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

	Not Done ◯
Fatigue	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Muscle Aches (Myalgia)	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Body Aches	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Headache	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
New Loss of Taste	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
New Loss of Smell	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ⬤
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	07 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 F

Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

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Not Done ◯

Fatigue None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

FDA-CBER-2022-1614-0616268

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Date of Visit	04 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ●
	No ○
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ○
	No ●
Date of Test	04 JAN 2021
Type of Test Performed	Nasopharyngeal Swab ●
	Nasal Swab ○
	Saliva Test ○
	Other ○
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ○
	No ●
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ○
	No ○
COVID-19 Positive (CSA Programming Field Only)	0

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Date of Contact	14 AUG 2020
Time of Contact	21:12
Date and Time of Contact (derived)	14 AUG 2020 21:12
Type of Contact	Clinic Visit - Scheduled ◯
	Clinical Visit - Unscheduled ⬤
	Safety Call ◯
	Convalescent Tele-visit ◯
Has the subject reported symptoms of SARS-COV-2?	Yes ⬤
	No ◯

Symptom Day

Day 1	●
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	○
Day 9	○
Day 10	○
Day 11	○
Day 12	○
Day 13	○
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	09 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue   None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)   None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches   None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache   None ◯

Mild ◯

Moderate ⬤

Severe ◯

Not Done ◯

New Loss of Taste   None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell   None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Runny Nose (Rhinorrhea)	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Nausea	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Vomiting	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Diarrhea	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Sore Throat	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	⭕
Day 2	⭕
Day 3	⭕
Day 4	⭕
Day 5	⭕
Day 6	⭕
Day 7	⚫
Day 8	⭕
Day 9	⭕
Day 10	⭕
Day 11	⭕
Day 12	⭕
Day 13	⭕
Day 14	⭕
Day 15	⭕
Day 16	⭕
Day 17	⭕
Day 18	⭕
Day 19	⭕
Day 20	⭕
Day 21	⭕
Day 22	⭕
Day 23	⭕
Day 24	⭕
Day 25	⭕
Day 26	⭕
Day 27	⭕
Day 28	⭕
Day 29	⭕
Day 30	⭕
Day 31	⭕
Day 32	⭕

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

	Day 33 ⭕
	Day 34 ⭕
	Day 35 ⭕
	Day 36 ⭕
	Day 37 ⭕
	Day 38 ⭕
	Day 39 ⭕
	Day 40 ⭕

Date	15 AUG 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Cough	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕

Not Done ◯

Fatigue

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ⬤

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ⬤

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ⬤

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Vomiting

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day	Day 1 ◯
	Day 2 ◯
	Day 3 ◯
	Day 4 ◯
	Day 5 ◯
	Day 6 ◯
	Day 7 ◯
	Day 8 ⬤
	Day 9 ◯
	Day 10 ◯
	Day 11 ◯
	Day 12 ◯
	Day 13 ◯
	Day 14 ◯
	Day 15 ◯
	Day 16 ◯
	Day 17 ◯
	Day 18 ◯
	Day 19 ◯
	Day 20 ◯
	Day 21 ◯
	Day 22 ◯
	Day 23 ◯
	Day 24 ◯
	Day 25 ◯
	Day 26 ◯
	Day 27 ◯
	Day 28 ◯
	Day 29 ◯
	Day 30 ◯
	Day 31 ◯
	Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	16 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

Day 1	○
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	○
Day 9	●
Day 10	○
Day 11	○
Day 12	○
Day 13	○
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	17 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.6 F

Chills
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ●

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **02 Apr 2021 18:02:49**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	⬤
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	18 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.3 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

Headache

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ○
- Mild ●
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Symptom Day

Day 1 ⬭
Day 2 ⬭
Day 3 ⬭
Day 4 ⬭
Day 5 ⬭
Day 6 ⬭
Day 7 ⬭
Day 8 ⬭
Day 9 ⬭
Day 10 ⬭
Day 11 ⬤
Day 12 ⬭
Day 13 ⬭
Day 14 ⬭
Day 15 ⬭
Day 16 ⬭
Day 17 ⬭
Day 18 ⬭
Day 19 ⬭
Day 20 ⬭
Day 21 ⬭
Day 22 ⬭
Day 23 ⬭
Day 24 ⬭
Day 25 ⬭
Day 26 ⬭
Day 27 ⬭
Day 28 ⬭
Day 29 ⬭
Day 30 ⬭
Day 31 ⬭
Day 32 ⬭

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	19 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ●

Fatigue

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nasal Congestion	
	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○

Runny Nose (Rhinorrhea)	
	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○

Nausea	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Vomiting	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Diarrhea	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Sore Throat	
	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Data signed: (b) (4) **02 Apr 2021 18:02:49**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	○
Day 2	○
Day 3	○
Day 4	○
Day 5	○
Day 6	○
Day 7	○
Day 8	○
Day 9	○
Day 10	○
Day 11	○
Day 12	●
Day 13	○
Day 14	○
Day 15	○
Day 16	○
Day 17	○
Day 18	○
Day 19	○
Day 20	○
Day 21	○
Day 22	○
Day 23	○
Day 24	○
Day 25	○
Day 26	○
Day 27	○
Day 28	○
Day 29	○
Day 30	○
Day 31	○
Day 32	○

	Day 33	◯
	Day 34	◯
	Day 35	◯
	Day 36	◯
	Day 37	◯
	Day 38	◯
	Day 39	◯
	Day 40	◯

Date	20 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

| | Not Done | ● |

Fatigue

	None	○
	Mild	●
	Moderate	○
	Severe	○
	Not Done	○

Muscle Aches (Myalgia)

	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

Body Aches

	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

Headache

	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

New Loss of Taste

	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

New Loss of Smell

	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

Nasal Congestion

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Runny Nose (Rhinorrhea)

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Nausea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Vomiting

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Diarrhea

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

Sore Throat

- None ●
- Mild ○
- Moderate ○
- Severe ○
- Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day	Day 1 ◯
	Day 2 ◯
	Day 3 ◯
	Day 4 ◯
	Day 5 ◯
	Day 6 ◯
	Day 7 ◯
	Day 8 ◯
	Day 9 ◯
	Day 10 ◯
	Day 11 ◯
	Day 12 ◯
	Day 13 ●
	Day 14 ◯
	Day 15 ◯
	Day 16 ◯
	Day 17 ◯
	Day 18 ◯
	Day 19 ◯
	Day 20 ◯
	Day 21 ◯
	Day 22 ◯
	Day 23 ◯
	Day 24 ◯
	Day 25 ◯
	Day 26 ◯
	Day 27 ◯
	Day 28 ◯
	Day 29 ◯
	Day 30 ◯
	Day 31 ◯
	Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	21 AUG 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

	Not Done ⚪
Fatigue	None ⚪
	Mild ⬤
	Moderate ⚪
	Severe ⚪
	Not Done ⚪
Muscle Aches (Myalgia)	None ⬤
	Mild ⚪
	Moderate ⚪
	Severe ⚪
	Not Done ⚪
Body Aches	None ⬤
	Mild ⚪
	Moderate ⚪
	Severe ⚪
	Not Done ⚪
Headache	None ⚪
	Mild ⬤
	Moderate ⚪
	Severe ⚪
	Not Done ⚪
New Loss of Taste	None ⬤
	Mild ⚪
	Moderate ⚪
	Severe ⚪
	Not Done ⚪
New Loss of Smell	None ⬤
	Mild ⚪
	Moderate ⚪
	Severe ⚪
	Not Done ⚪

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ⬤
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	22 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ●

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ●

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ●

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ◯
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ⬤
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	23 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

	Not Done	○
Fatigue	None	○
	Mild	●
	Moderate	○
	Severe	○
	Not Done	○
Muscle Aches (Myalgia)	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○
Body Aches	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○
Headache	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○
New Loss of Taste	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○
New Loss of Smell	None	●
	Mild	○
	Moderate	○
	Severe	○
	Not Done	○

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

Day 1	⬭
Day 2	⬭
Day 3	⬭
Day 4	⬭
Day 5	⬭
Day 6	⬭
Day 7	⬭
Day 8	⬭
Day 9	⬭
Day 10	⬭
Day 11	⬭
Day 12	⬭
Day 13	⬭
Day 14	⬭
Day 15	⬭
Day 16	⬭
Day 17	⬤
Day 18	⬭
Day 19	⬭
Day 20	⬭
Day 21	⬭
Day 22	⬭
Day 23	⬭
Day 24	⬭
Day 25	⬭
Day 26	⬭
Day 27	⬭
Day 28	⬭
Day 29	⬭
Day 30	⬭
Day 31	⬭
Day 32	⬭

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	25 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.8 F

Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Muscle Aches (Myalgia) None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Body Aches None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Headache None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Taste None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

New Loss of Smell None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Runny Nose (Rhinorrhea)

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Nausea

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Vomiting

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Diarrhea

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Sore Throat

- None ⬤
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	⬤
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	24 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nasal Congestion

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	⬤
Day 3	◯
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	10 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ◯

Fatigue

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Runny Nose (Rhinorrhea)

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Nausea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Vomiting

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Diarrhea

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

Sore Throat

None ⬭
Mild ⬭
Moderate ⬭
Severe ⬭
Not Done ⬭

US3212066

Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) **02 Apr 2021 18:02:49**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	⬤
Day 4	◯
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	11 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ⬭

Fatigue

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Muscle Aches (Myalgia)

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Body Aches

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Headache

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Taste

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

New Loss of Smell

None ⬭

Mild ⬭

Moderate ⬭

Severe ⬭

Not Done ⬭

Nasal Congestion

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Runny Nose (Rhinorrhea)

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Nausea

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Vomiting

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Diarrhea

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

Sore Throat

None ⚪
Mild ⚪
Moderate ⚪
Severe ⚪
Not Done ⚪

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	⬤
Day 5	◯
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	12 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ○

Fatigue

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ○

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Runny Nose (Rhinorrhea)

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Nausea

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Vomiting

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Diarrhea

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

Sore Throat

None ⭕
Mild ⭕
Moderate ⭕
Severe ⭕
Not Done ⭕

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **02 Apr 2021 18:02:49**
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1	◯
Day 2	◯
Day 3	◯
Day 4	◯
Day 5	⬤
Day 6	◯
Day 7	◯
Day 8	◯
Day 9	◯
Day 10	◯
Day 11	◯
Day 12	◯
Day 13	◯
Day 14	◯
Day 15	◯
Day 16	◯
Day 17	◯
Day 18	◯
Day 19	◯
Day 20	◯
Day 21	◯
Day 22	◯
Day 23	◯
Day 24	◯
Day 25	◯
Day 26	◯
Day 27	◯
Day 28	◯
Day 29	◯
Day 30	◯
Day 31	◯
Day 32	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	13 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	

Chills	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	
	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

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Not Done ◯

Fatigue

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ◯

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ◯
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) **02 Apr 2021 18:02:49**

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Day 1 ◯
Day 2 ◯
Day 3 ◯
Day 4 ◯
Day 5 ◯
Day 6 ●
Day 7 ◯
Day 8 ◯
Day 9 ◯
Day 10 ◯
Day 11 ◯
Day 12 ◯
Day 13 ◯
Day 14 ◯
Day 15 ◯
Day 16 ◯
Day 17 ◯
Day 18 ◯
Day 19 ◯
Day 20 ◯
Day 21 ◯
Day 22 ◯
Day 23 ◯
Day 24 ◯
Day 25 ◯
Day 26 ◯
Day 27 ◯
Day 28 ◯
Day 29 ◯
Day 30 ◯
Day 31 ◯
Day 32 ◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	14 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	97.5 F

Chills
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Cough
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Shortness of Breath
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯
- Not Done ◯

Difficulty Breathing
- None ●
- Mild ◯
- Moderate ◯
- Severe ◯

	Not Done ◯
Fatigue	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯
Muscle Aches (Myalgia)	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Body Aches	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Headache	None ◯
	Mild ◯
	Moderate ●
	Severe ◯
	Not Done ◯
New Loss of Taste	None ◯
	Mild ◯
	Moderate ●
	Severe ◯
	Not Done ◯
New Loss of Smell	None ◯
	Mild ◯
	Moderate ●
	Severe ◯
	Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Vomiting

None ○
Mild ○
Moderate ●
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Date of Visit	14 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR?　　Yes ●

No ○

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?　　Yes ●

No ○

Date of Test	14 AUG 2020

Type of Test Performed　　Nasopharyngeal Swab ●

Nasal Swab ○

Saliva Test ○

Other ○

　Other, specify　　_____

Was this diagnostic test performed at a lab other than the Study Central Lab?　　Yes ○

No ●

If yes, provide lab information below

Lab/ Institution Test Performed　　_____

CLIA Certified?　　Yes ○

No ○

COVID-19 Positive (CSA Programming Field Only)	1

Did the subject have Respiratory Rates $\geq$ 30 per Minute? Yes ◯ No ⬤

If Yes, provide:

  Start Date

  End Date

  Respiratory Rate

Did the subject have Heart Rate $\geq$ 125 beats per minute Yes ◯ No ⬤

If Yes, provide:

  Start Date

  End Date

  Heart Rate

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level? Yes ◯ No ⬤

If Yes, provide:

  Start Date

  End Date

  Oxygen Saturation

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg? Yes ◯ No ⬤

If Yes, provide:

  Start Date

  End Date

  PaO2

Did the subject have Respiratory failure? Yes ◯ No ⬤

  Start Date

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ◯ No ⬤

  Start Date

FDA-CBER-2022-1614-0616340

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?	Yes ◯
	No ◯
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ◯
	No ◯
Start Date	
End Date	
Mechanical Ventilation?	Yes ◯
	No ◯
Start Date	
End Date	
ECMO?	Yes ◯
	No ◯
Start Date	
End Date	

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ◯
	No ●
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ◯
	No ●
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ◯
	No ●
Start Date	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Data signed: (b) (4) **02 Apr 2021 18:02:48**
Generated On: 11 Aug 2021 22:07:04

Hepatic Dysfunction?	Yes ◯
	No ⬤
Start Date	
Neurologic Dysfunction?	Yes ◯
	No ⬤
Start Date	

Evidence of Pneumonia:

Clinical Evidence	Yes ◯
	No ⬤
Date of Assessment	
Radiographical Evidence	Yes ◯
	No ◯
Date of Assessment	

Admission to an intensive care unit due to SARS-CoV-2	Yes ◯
	No ⬤
Start Date	
End Date	

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Generate Next COVID-19 Assessment   Yes ◯

No ⬤

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 AUG 2020
Day 5	Yes	18 AUG 2020
Day 7	Yes	20 AUG 2020
Day 9	Yes	22 AUG 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	06 JAN 2021
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)	

US3212066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SICKD1

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	14 AUG 2020
Time of assessment *(00:00-23:59)*	21:13 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 21:13
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	148 lb
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 18:02:51**
Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ○
	NA (COVID-19 Negative) ○
Date of Collection	14 AUG 2020

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes	◯
	No	◯

Visit date (dd MMM yyyy)

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

Folder OID

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Height *(xxx.x)*	_____
Weight *(xxx.x)*	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3212066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection _____

Was this visit performed?   Yes ◯

                                                                  No ◯

Visit date (dd MMM yyyy)   _____

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

                                                                  Clinic ◯

Folder OID   _____

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Height *(xxx.x)*	_____
Weight *(xxx.x)*	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

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.

US3212066

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection _____

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes	◯
	No	◯

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Height *(xxx.x)*	_____
Weight *(xxx.x)*	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

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.

US3212066

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection _____

US3212066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	04 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SICKD1

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	04 JAN 2021
Time of assessment *(00:00-23:59)*	12:20 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 12:20
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?   Yes ●

    No ◯

Date of examination *(dd MMM yyyy)*   04 JAN 2021

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

US3212066

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯

| Date of Collection | 04 JAN 2021 |

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

| Was this visit performed? | Yes ◯ |
| | No ⬤ |

Visit date (dd MMM yyyy) _____

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

Folder OID   SICKD28

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ⭕
	No 🔘
	NA (COVID-19 Negative) ⭕

Date of Collection

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes	◯
	No	◯

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

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

Yes ⬭

No ⬭

NA (COVID-19 Negative) ⬭

Date of Collection _____

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ◯
	No ◯

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes	◯
	No	◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral	◯
	Axillary	◯
	Other	◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection _____

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?   Yes ◯
                                                                            No ◯

Visit date (dd MMM yyyy)   _____

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

Folder OID   _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ◯
	No ◯

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ◯
	NA (COVID-19 Negative) ◯

Date of Collection _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?　　　　　　　　　　　　　　　　Yes ◯

　　　　　　　　　　　　　　　　　　　　　　　　　　　No ⬤

Visit date (dd MMM yyyy)

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

　　　　　　　　　　　　　　　　　　　　　　　　　Clinic ◯

Folder OID　　　　　　　　　　　　　　　　　　　　SICKD28

| Were vital signs assessed? | Yes ⭕ |
| | No ⬤ |

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ⭕
	Axillary ⭕
	Other ⭕

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

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.

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

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

Yes ◯

No ◯

NA (COVID-19 Negative) ●

Date of Collection

US3212066

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

Form: Visit Date

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes	●
	No	○

Visit date (dd MMM yyyy)	28 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **22 Apr 2021 19:25:20**
Generated On: 11 Aug 2021 22:07:04

Date of updated informed consent *(dd MMM yyyy)*	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	28 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3212066

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Height	
Weight	
BMI (xxx.x)	

US3212066

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Height	_____
Weight	_____
BMI *(xxx.x)*	_____
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	28 JAN 2021
Time of assessment *(00:00-23:59)*	10:52 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 10:52
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	_____
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3212066

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 18:02:51

Generated On: 11 Aug 2021 22:07:04

Height	
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬭
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⬭
Date of assessment *(dd MMM yyyy)*	28 JAN 2021
Time of assessment *(00:00-23:59)*	12:11 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 12:11
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3212066

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

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?	Yes ●
	No ○

Date of examination *(dd MMM yyyy)*	28 JAN 2021

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

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	28 JAN 2021
What was the treatment time? *(00:00-23:59)*	11:35 (24 HR)
Treatment Date and Time (derived)	28 JAN 2021 11:35
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0616392

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	28 JAN 2021
Collection time *(00:00-23:59)*	11:10 (24 HR)
Collection date and time (derived)	28 JAN 2021 11:10

US3212066

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	28 JAN 2021
Collection time *(00:00 - 23:59)*	11:05
Collection Date and Time (derived)	28 JAN 2021 11:05

US3212066

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

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3212066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 04 FEB 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3212066
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 18:02:52**
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

OLD29 Placebo Flag   1

Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 18:02:51**
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	OLD29

US3212066
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **02 Apr 2021 18:02:51**
Generated On: 11 Aug 2021 22:07:04

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	12:41 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:41
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	14:21 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:21
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3212066

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?　　　　　　　Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*　　　　　　　　　26 FEB 2021

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

Was study treatment given?   Yes ●

                                                                                     No ○

If No, reason not given

Participant declined due to Adverse Event ○

Physician withheld dose due to Adverse Event ○

Death ○

Lost To Follow-Up ○

Physician Decision ○

Pregnancy ○

Protocol Deviation ○

Study Terminated by Sponsor ○

Withdrawal of Consent by Participant ○

Confirmed COVID-19 ○

Other ○

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

What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	26 FEB 2021
What was the treatment time? *(00:00-23:59)*	13:42 (24 HR)
Treatment Date and Time (derived)	26 FEB 2021 13:42

Which arm was used to give treatment?   Left Arm ●

                                                                               Right Arm ○

What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3212066
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 18:02:51**
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3212066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	05 MAR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3212066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3212066
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 18:02:51**
Generated On: 11 Aug 2021 22:07:04

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | OLD57 |

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	01 APR 2021
Time of assessment *(00:00-23:59)*	10:08 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 10:08
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) **02 Apr 2021 18:02:51**

Generated On: 11 Aug 2021 22:07:04

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.

Was the sample collected?   Yes ◯

                                                                             No ⬤

Collection date *(dd MMM yyyy)*

Collection time *(00:00-23:59)*

Collection date and time (derived)

US3212066

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **31 Mar 2021 00:55:09**

Generated On: 11 Aug 2021 22:07:04

Did the participant experience any adverse events?　　　　Yes ⬤

　　　　No ◯

If Yes, enter details on the Adverse Events form.

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **22 Apr 2021 19:25:20**

Generated On: 11 Aug 2021 22:07:04

AEID	USA-US115-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19

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)*	09 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	25 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　Grade 1/Mild ○　Grade 2/Moderate ●　Grade 3/Severe ○　Grade 4 ○

Is the adverse event serious?　Yes ○ No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?　Yes ○ No ○ Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ⬤
- Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

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

Narrative

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **22 Apr 2021 19:25:20**

Generated On: 11 Aug 2021 22:07:04

	SUBJECT TESTED POSITIVE FOR COVID19 AT BASELINE/SCREENING VISIT; LAB RESULTS RECEIVED 13AUG2020. ILLNESS VISIT AND CONVALESCENT VISITS BEGAN 14AUG2020. SUBJECT IS A HOSPITAL WORKER AND COHABITATES WITH SOMEONE WORKING A HIGH OCCUPATIONAL RISK JOB. SUBJECT REPORTS FATIGUE, INTERMITTENT SINUS HEADACHE SOMETIMES REACHING 6/10 ON PAIN SCALE, COMPLETE LOSS OF TASTE AND SMELL, AND NAUSEA. ALL SYMPTOMS RESOLVED BY 25AUG2020
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	ACUTE SINUSITIS
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)*	28 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	02 JAN 2021
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	

US3212066

Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **22 Apr 2021 19:25:20**
Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ⬤
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	HUMAN ENTEROVIRUS/RHINOVIRUS

| 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)*	24 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

| Ongoing? | Yes ◯ |
| | No ⬤ |

If not Ongoing, end date *(dd MMM yyyy)*	02 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯

| Is the adverse event serious? | Yes ◯ |
| | No ⬤ |

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ○
- Related ○
- Not Applicable ●

Action taken with investigational product

- None ●
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ○

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

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)	

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes ⚪
	No ⚫
Was this a Solicited Adverse Reaction?	Yes ⚫
	No ⚪
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ⚪
	No ⚫
Start date *(dd MMM yyyy)*	07 AUG 2020
Start time *(00:00-23:59)*	12:12 (24 HR)
AE start date and time (derived)	07 AUG 2020 12:12
Ongoing?	Yes ⚪
	No ⚫
If not Ongoing, end date *(dd MMM yyyy)*	16 AUG 2020
End time *(00:00-23:59)*	13:32 (24 HR)
AE End Date and Time (derived)	16 AUG 2020 13:32
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	

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 19:25:20

Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ⭕
	Related ⬤
	Not Applicable ⭕

Relationship to Study Procedure	Not Related ⭕
	Related ⬤
	Not Applicable ⭕

Action taken with investigational product	None ⬤
	Dose Delayed ⭕
	Investigational Product Withdrawn ⭕
	Not Applicable ⭕

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal ⭕
	Not Recovered/Not Resolved ⭕
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ⭕
	Recovering/Resolving ⭕
	Unknown ⭕

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

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

No ○

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	LISINOPRIL

Prophylaxis	Yes	⚪
	No	⬤

Indication	HYPERTENSION
Dose per administration	5

Dose unit	mg	⬤
	ug	⚪
	mL	⚪
	g	⚪
	IU	⚪
	tablet	⚪
	capsule	⚪
	puff	⚪
	Other	⚪

If dose unit is Other, specify

Frequency	once daily	⬤
	twice daily	⚪
	three times daily	⚪
	four times daily	⚪
	every other day	⚪
	every week	⚪
	every month	⚪
	as needed	⚪
	once	⚪
	unknown	⚪
	other	⚪

If frequency is Other, specify

Route of administration	Oral	⬤
	Topical	⚪
	Subcutaneous	⚪
	Transdermal	⚪
	Intraocular	⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	PROPANALOL

Prophylaxis	
Yes	○
No	●

Indication	HEADACHES
Dose per administration	5

Dose unit	
mg	●
ug	○
mL	○
g	○
IU	○
tablet	○
capsule	○
puff	○
Other	○

If dose unit is Other, specify

Frequency	
once daily	○
twice daily	○
three times daily	○
four times daily	○
every other day	○
every week	○
every month	○
as needed	●
once	○
unknown	○
other	○

If frequency is Other, specify

Route of administration	
Oral	●
Topical	○
Subcutaneous	○
Transdermal	○
Intraocular	○

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	ACETAMINOPHEN

Prophylaxis

Yes ⚪
No ⚫

Indication	HEADACHES
Dose per administration	500

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify _____

Frequency

once daily ⚪
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚫
once ⚪
unknown ⚪
other ⚪

If frequency is Other, specify _____

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	09 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ●
	No ◯
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Name of Medication	PREDNISONE
Prophylaxis	Yes ○
	No ●
Indication	COVID-19
Dose per administration	50
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	10 AUG 2020
Start date completely unknown	False

Ongoing?

Yes ◯

No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	15 AUG 2020

Was this medication taken for solicited event?

Yes ◯

No ⬤

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1

Interval Dosage Definition (derived)

802 ◯

803 ◯

804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	TYLENOL

Prophylaxis

Yes ◯
No ⬤

Indication	HEADACHE
Dose per administration	650

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ⬤
once ◯
unknown ◯
other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

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EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	09 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	TOPIRAMATE

Prophylaxis	Yes ◯
	No ⬤

Indication	MIGRAINE HEADACHES

Dose per administration	50

Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify	

Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Name of Medication	IMITREX
Prophylaxis	Yes ⚪
	No ⬤
Indication	MIGRAINE HEADACHES
Dose per administration	50
Dose unit	mg ⬤
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⬤
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	07 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ●
	No ○
Indication	IMMUNIZATION
Dose per administration	0.5
Dose unit	mg ○
	ug ○
	mL ●
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	●
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	06 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	06 NOV 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Name of Medication	PREDNISONE

Prophylaxis	
Yes	○
No	●

Indication	ACUTE SINUSITIS
Dose per administration	20

Dose unit	
mg	●
ug	○
mL	○
g	○
IU	○
tablet	○
capsule	○
puff	○
Other	○

If dose unit is Other, specify _____

Frequency	
once daily	○
twice daily	○
three times daily	●
four times daily	○
every other day	○
every week	○
every month	○
as needed	○
once	○
unknown	○
other	○

If frequency is Other, specify _____

Route of administration	
Oral	●
Topical	○
Subcutaneous	○
Transdermal	○
Intraocular	○

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **02 Apr 2021 18:02:47**
Generated On: 11 Aug 2021 22:07:04

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **02 Apr 2021 18:02:47**

Generated On: 11 Aug 2021 22:07:04

Name of Medication	PREDNISONE

Prophylaxis	
Yes	⚪
No	⬤

Indication	ACUTE SINUSITIS

Dose per administration	20

Dose unit	
mg	⬤
ug	⚪
mL	⚪
g	⚪
IU	⚪
tablet	⚪
capsule	⚪
puff	⚪
Other	⚪

If dose unit is Other, specify	

Frequency	
once daily	⚪
twice daily	⬤
three times daily	⚪
four times daily	⚪
every other day	⚪
every week	⚪
every month	⚪
as needed	⚪
once	⚪
unknown	⚪
other	⚪

If frequency is Other, specify	

Route of administration	
Oral	⬤
Topical	⚪
Subcutaneous	⚪
Transdermal	⚪
Intraocular	⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	02 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 18:02:47

Generated On: 11 Aug 2021 22:07:04

Name of Medication	ZITHROMAX

Prophylaxis	Yes ⭘
	No ⬤

Indication	ACUTE SINUSITIS
Dose per administration	500

Dose unit	mg ⬤
	ug ⭘
	mL ⭘
	g ⭘
	IU ⭘
	tablet ⭘
	capsule ⭘
	puff ⭘
	Other ⭘

If dose unit is Other, specify	

Frequency	once daily ⬤
	twice daily ⭘
	three times daily ⭘
	four times daily ⭘
	every other day ⭘
	every week ⭘
	every month ⭘
	as needed ⭘
	once ⭘
	unknown ⭘
	other ⭘

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ⭘
	Subcutaneous ⭘
	Transdermal ⭘
	Intraocular ⭘

	Intramuscular	◯
	Respiratory (Inhalation)	◯
	Intralesional	◯
	Intraperiteoneal	◯
	Nasal	◯
	Vaginal	◯
	Rectal	◯
	Intravenous	◯
	Intravenous Bolus	◯
	Intravenous Drip	◯
	Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	02 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3212066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **02 Apr 2021 18:02:48**

Generated On: 11 Aug 2021 22:07:04

Were any concomitant procedures performed?   Yes ◯

                                                              No ●

If yes, please complete Concomitant Procedures form.

Date of dosing discontinuation (dd MMM yyyy)	13 AUG 2020
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	COVID-19 POSITIVE RESULTS

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	◯

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Data signed: (b) (4) **02 Apr 2021 18:02:52**
Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ●
Death	Yes ◯ No ●
Life threatening	Yes ◯ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ●
Persistent or significant disability or incapacity	Yes ◯ No ●
Congenital anomaly or birth defect	Yes ◯ No ●
Other medically important event	Yes ◯ No ●
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/AUG/2020 15:36
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

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/AUG/2020 14:42
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

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Data signed: (b) (4) **02 Apr 2021 18:02:52**
Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/SEP/2020 16:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) **02 Apr 2021 18:02:52**

Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/SEP/2020 10:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Data signed: (b) (4) **02 Apr 2021 18:02:52**
Generated On: 11 Aug 2021 22:07:04

SAEID	USA-US115-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:51
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

US3212066 (Prod: DM Clinical Research - ERN - PPDS)

US3212066

Form: Participant Creation

Generated On: 11 Aug 2021 22:07:04

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'US3212066'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:18

US3212066
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:33

US3212066
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:04:00
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:18

US3212066

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:33

US3212066
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'SCRN'	System	06 Aug 2020 16:41:33

US3212066

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:07:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered (b) (6) 1976'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:19

US3212066

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:07:04

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '43'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'YEARS'	System	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '43'	System	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:07:04

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Female (F)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '1'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:07:04

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:07:04

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:07:04
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:41:48

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:11:47
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Aug 2020'	System	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2020'	System	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
(b) (4)		
User entered 'Amendment 1 (1)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:02

US3212066

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:07:04

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:18

US3212066
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:07:04
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '1'	System	06 Aug 2020 16:42:09

US3212066

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:07:04

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:09

US3212066

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:07:04

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:31

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
Data point term sent to Coder	System	06 Aug 2020 16:43:30
User entered 'HYPERTENSION'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2015'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2015'	System	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2015'	System	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:07:04

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	06 Aug 2020 16:42:49

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
Data point term sent to Coder	System	06 Aug 2020 16:43:31
User entered 'UTERINE ABLATION'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2017'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2017'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

FDA-CBER-2022-1614-0616499

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2017'	System	06 Aug 2020 16:43:09

US3212066

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:07:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2017'	System	06 Aug 2020 16:43:09

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2017'	System	06 Aug 2020 16:43:09

US3212066
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:07:04
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2017'	System	06 Aug 2020 16:43:09

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:44:16
Data point term sent to Coder	System	06 Aug 2020 16:43:33
User entered 'MENORRHAGIA'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2011'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2017'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:31

US3212066
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:07:04
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2011'	System	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2011'	System	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2017'	System	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:07:04

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2017'	System	06 Aug 2020 16:43:31

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 16:45:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:45:18
Data point term sent to Coder	System	06 Aug 2020 16:44:34
User entered 'HEADACHES'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'UN UNK 2018'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
	(b) (4)	
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'Jan 2018'	System	06 Aug 2020 16:43:43

US3212066
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:07:04
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '2018'	System	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:07:04

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	06 Aug 2020 16:43:43

US3212066
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:07:04

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	06 Aug 2020 16:43:43

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
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.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:43:26
Data point term sent to Coder	System	27 Aug 2020 17:44:16
User entered 'Bilateral tubal ligation'	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '1'	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '1'	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:02

US3212066
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:07:04
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:07:04

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered empty.	System	27 Aug 2020 17:44:02

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:11:58
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '10:48'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered '06 Aug 2020 10:48'	System	04 Dec 2020 16:11:58
User entered '6 Aug 2020 10:48'	System	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '63' in	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42
DataPoint set to visible.	System	06 Aug 2020 16:42:09

Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '148.6' lb	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42
DataPoint set to visible.	System	06 Aug 2020 16:42:09

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
Amendment Manager: User entered '26.37835'	System	16 Sep 2020 23:45:43
User entered '26.4'	System	06 Aug 2020 16:46:42
DataPoint set to visible.	System	06 Aug 2020 16:42:09

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'kg/m2'	System	06 Aug 2020 16:46:42
DataPoint set to visible.	System	06 Aug 2020 16:42:09

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 17:14:56
User entered 'Other (Other)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 17:14:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered '87'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'bpm'	System	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered '15'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'breaths/min'	System	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered '121'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'mmHg'	System	06 Aug 2020 16:46:42

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:46
User entered '81'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User entered 'mmHg'	System	06 Aug 2020 16:46:42

US3212066
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40

US3212066

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40

US3212066

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:56

US3212066

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4) Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:12:04
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:51:19
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 16:45:43
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:49:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Aug 2020 19:27:25
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:46:56

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:12:10
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

Folder: Screening
Form: Childbearing Potential
Generated On: 11 Aug 2021 22:07:04
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User closed query 'Per DM CLR: If No, what is the reason? = Other/BILATERAL TUBAL LIGATION. Please review if 'Surgically sterile' should be a more appropriate response. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 16:28:47
Query 'Per DM CLR: If No, what is the reason? = Other/BILATERAL TUBAL LIGATION. Please review if 'Surgically sterile' should be a more appropriate response. Update as appropriate.' answered with 'Updated MH' (Site from DM).	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:14
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:42:39
User opened query 'Per DM CLR: If No, what is the reason? = Other/BILATERAL TUBAL LIGATION. Please review if 'Surgically sterile' should be a more appropriate response. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 05:59:48
User entered 'Other (OTHER)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 16:30:14
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' answered with 'Updated MH' (Site from DM).	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:44:24
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:42:39
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 05:59:46
User entered 'Bilateral Tubal Ligation'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:42:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:07:04

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:47:28

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'RESEARCH ADMINISTRATION'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:07:04
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:07:04
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:07:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '1'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:07:04
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:24:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Participant goes in person to their main workplace more than 2 days/week. Participant lives with children in the household likely to go back to school in person this year...'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:17

US3212066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:28

US3212066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	10 Nov 2020 14:05:00
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:28

US3212066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:48:28

US3212066
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'VISIT1'	System	06 Aug 2020 16:48:28

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:20

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:34:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:34:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 16:39:20
User entered '101645' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:20

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:39:20

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:00

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:00

US3212066

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:07:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:00

US3212066
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:07:04

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:00

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:07:04
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:07:04
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:13:52
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '10:48'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '06 Aug 2020 10:48'	System	04 Dec 2020 16:13:52
User entered '6 Aug 2020 10:48'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '87'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'bpm'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '15'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'breaths/min'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '121'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '81'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:07:04
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:07:04
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:13:52
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 15:49:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.' (Site from System).	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:13
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	06 Aug 2020 20:05:02
User entered '12:58'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '06 Aug 2020 12:58'	System	04 Dec 2020 16:13:52
User entered '6 Aug 2020 12:58'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '98.4' F	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '86'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'bpm'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '12'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'breaths/min'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '104'	(b) (4) Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 11:01:44
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 20:00:16
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:45:43
User entered '51'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	06 Aug 2020 20:05:02

US3212066

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:11

US3212066

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:32:01
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:49:11

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

US3212066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:24:12

US3212066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User closed query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 21:51:35
Query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'updated' (Site from DM).	Heather Leary (b) (4) (b) (4)	06 Nov 2020 20:42:06
User entered '06 Aug 2020' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	06 Nov 2020 20:42:01
User opened query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:41:22
User entered '6 Aug 2020'	Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '12:23'	Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '06 Aug 2020 12:23'	System	06 Nov 2020 20:42:01
User entered '6 Aug 2020 12:23'	System	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Heather Leary (b) (4) (b) (4)	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:07:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'ONCE'	System	06 Aug 2020 17:24:12

US3212066

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:24:12

US3212066
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:07:04
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:06:11

US3212066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 21:39:29
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:06:11

US3212066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '11:51'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:06:11

US3212066

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '06 Aug 2020 11:51'	System	04 Dec 2020 21:39:29
User entered '6 Aug 2020 11:51'	System	06 Aug 2020 17:06:11

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '06 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:14:10
User entered '6 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

US3212066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:07:04

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

US3212066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '11:40'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '06 Aug 2020 11:40'	System	04 Dec 2020 16:14:10
User entered '6 Aug 2020 11:40'	System	06 Aug 2020 17:05:50

US3212066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:07:04

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

US3212066

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:16:35
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:16:35
User entered '11:40'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 17:05:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	25 Aug 2020 20:16:35
User entered '6 Aug 2020 11:40'	System	06 Aug 2020 17:05:50

US3212066
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	18 Aug 2020 20:00:45

US3212066
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	18 Aug 2020 20:00:45

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:51:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3094b31e-1031-4295-8f1c-c453b1728bff'	System	06 Aug 2020 17:52:16
User entered 'Yes (Y)'	System	06 Aug 2020 17:52:16

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3094b31e-1031-4295-8f1c-c453b1728bff'	System	06 Aug 2020 17:52:16
User entered '98.4'	System	06 Aug 2020 17:52:16

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3094b31e-1031-4295-8f1c-c453b1728bff'	System	06 Aug 2020 17:52:16
User entered 'No (N)'	System	06 Aug 2020 17:52:16

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3094b31e-1031-4295-8f1c-c453b1728bff'	System	06 Aug 2020 17:52:16
User entered '06 Aug 2020 12:52'	System	06 Aug 2020 17:52:16

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 12:43'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 15:13'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:49:53', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5d5220d7-7b56-42bc-9880-5741fe2ef0f5'	System	06 Aug 2020 22:50:08
User entered 'Yes (Y)'	System	06 Aug 2020 22:50:08

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:49:57', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5d5220d7-7b56-42bc-9880-5741fe2ef0f5'	System	06 Aug 2020 22:50:08
User entered '99.1'	System	06 Aug 2020 22:50:08

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:01', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5d5220d7-7b56-42bc-9880-5741fe2ef0f5'	System	06 Aug 2020 22:50:08
User entered 'No (N)'	System	06 Aug 2020 22:50:08

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5d5220d7-7b56-42bc-9880-5741fe2ef0f5'	System	06 Aug 2020 22:50:08
User entered '06 Aug 2020 17:50'	System	06 Aug 2020 22:50:08

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 16:08'	System	06 Aug 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 2'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:07:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:14:38', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8bbf5578-de2b-4b4d-948e-7239727f1467'	System	07 Aug 2020 17:14:53
User entered 'Yes (Y)'	System	07 Aug 2020 17:14:53

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:14:42', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8bbf5578-de2b-4b4d-948e-7239727f1467'	System	07 Aug 2020 17:14:53
User entered '97.2'	System	07 Aug 2020 17:14:53

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:14:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8bbf5578-de2b-4b4d-948e-7239727f1467'	System	07 Aug 2020 17:14:53
User entered 'No (N)'	System	07 Aug 2020 17:14:53

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:14:48', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8bbf5578-de2b-4b4d-948e-7239727f1467'	System	07 Aug 2020 17:14:53
User entered '07 Aug 2020 12:14'	System	07 Aug 2020 17:14:53

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 3'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:07:04
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:15', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c36ce438-073f-4a1c-a4bf-b2bad073be9c'	System	09 Aug 2020 02:40:31
User entered 'Yes (Y)'	System	09 Aug 2020 02:40:31

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:21', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c36ce438-073f-4a1c-a4bf-b2bad073be9c'	System	09 Aug 2020 02:40:31
User entered '98.6'	System	09 Aug 2020 02:40:31

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:24', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c36ce438-073f-4a1c-a4bf-b2bad073be9c'	System	09 Aug 2020 02:40:31
User entered 'No (N)'	System	09 Aug 2020 02:40:31

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:27', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c36ce438-073f-4a1c-a4bf-b2bad073be9c'	System	09 Aug 2020 02:40:31
User entered '08 Aug 2020 21:40'	System	09 Aug 2020 02:40:31

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 4'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:07:04
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered 'Yes (Y)'	System	09 Aug 2020 23:07:22

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:59', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered '98.3'	System	09 Aug 2020 23:07:22

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:07:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered 'Yes (Y)'	System	09 Aug 2020 23:07:22

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:07:04
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:19:25
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 and conmeds updated' (Site from System).	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Aug 2020 23:07:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:07:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered '1'	System	09 Aug 2020 23:07:22

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:07:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:07:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered '0'	System	09 Aug 2020 23:07:22

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:07:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '81a22155-157d-400c-8721-a5515d22f6cb'	System	09 Aug 2020 23:07:22
User entered '09 Aug 2020 18:07'	System	09 Aug 2020 23:07:22

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 5'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:27', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered 'Yes (Y)'	System	10 Aug 2020 23:05:54

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:34', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered '97.5'	System	10 Aug 2020 23:05:54

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:41', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered 'Yes (Y)'	System	10 Aug 2020 23:05:54

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:07:04
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:19:39
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 and conmeds updated' (Site from System).	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Aug 2020 23:05:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered '1'	System	10 Aug 2020 23:05:54

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered '0'	System	10 Aug 2020 23:05:54

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5ed5692-bef8-4ce4-b9c3-28d127485e91'	System	10 Aug 2020 23:05:54
User entered '10 Aug 2020 18:05'	System	10 Aug 2020 23:05:54

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 6'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:07:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:02', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered 'Yes (Y)'	System	11 Aug 2020 22:51:26

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered '97.9'	System	11 Aug 2020 22:51:26

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered 'Yes (Y)'	System	11 Aug 2020 22:51:26

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:21:48
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 'Subject was contacted, medication already listed in concomitant medications; patient takes as needed ' (Site from System).	Heather Leary (b) (4) (b) (4)	12 Aug 2020 14:47:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Aug 2020 22:51:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered '1'	System	11 Aug 2020 22:51:26

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:07:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered '0'	System	11 Aug 2020 22:51:26

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:19', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0b455c15-4a25-4e43-afae-a3f5f03a206c'	System	11 Aug 2020 22:51:26
User entered '11 Aug 2020 17:51'	System	11 Aug 2020 22:51:26

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 7'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:07:04
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:18:02', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7f6221e2-62b0-4481-a065-8ecfd3559f3b'	System	12 Aug 2020 23:18:23
User entered 'Yes (Y)'	System	12 Aug 2020 23:18:23

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:07:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:18:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7f6221e2-62b0-4481-a065-8ecfd3559f3b'	System	12 Aug 2020 23:18:23
User entered '98.6'	System	12 Aug 2020 23:18:23

US3212066

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:18:17', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7f6221e2-62b0-4481-a065-8ecfd3559f3b'	System	12 Aug 2020 23:18:23
User entered 'No (N)'	System	12 Aug 2020 23:18:23

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:18:19', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7f6221e2-62b0-4481-a065-8ecfd3559f3b'	System	12 Aug 2020 23:18:23
User entered '12 Aug 2020 18:18'	System	12 Aug 2020 23:18:23

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:33', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'bf341c1f-fff6-4022-b99a-82841c682fa6'	System	06 Aug 2020 17:52:56
User entered 'None (1)'	System	06 Aug 2020 17:52:56

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:38', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'bf341c1f-fff6-4022-b99a-82841c682fa6'	System	06 Aug 2020 17:52:56
User entered 'No (N)'	System	06 Aug 2020 17:52:56

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'bf341c1f-fff6-4022-b99a-82841c682fa6'	System	06 Aug 2020 17:52:56
User entered 'No (N)'	System	06 Aug 2020 17:52:56

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'bf341c1f-fff6-4022-b99a-82841c682fa6'	System	06 Aug 2020 17:52:56
User entered 'None (1)'	System	06 Aug 2020 17:52:56

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:52:53', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'bf341c1f-fff6-4022-b99a-82841c682fa6'	System	06 Aug 2020 17:52:56
User entered '06 Aug 2020 12:52'	System	06 Aug 2020 17:52:56

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 12:43'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 15:13'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T16:09:32', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '442ccd44-af63-4ffe-adae-4e5990926fe0'	System	06 Aug 2020 21:09:47
User entered 'None (1)'	System	06 Aug 2020 21:09:47

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T16:09:35', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '442ccd44-af63-4ffe-adae-4e5990926fe0'	System	06 Aug 2020 21:09:47
User entered 'No (N)'	System	06 Aug 2020 21:09:47

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T16:09:37', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '442ccd44-af63-4ffe-adae-4e5990926fe0'	System	06 Aug 2020 21:09:47
User entered 'No (N)'	System	06 Aug 2020 21:09:47

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T16:09:40', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '442ccd44-af63-4ffe-adae-4e5990926fe0'	System	06 Aug 2020 21:09:47
User entered 'None (1)'	System	06 Aug 2020 21:09:47

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T16:09:43', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '442ccd44-af63-4ffe-adae-4e5990926fe0'	System	06 Aug 2020 21:09:47
User entered '06 Aug 2020 16:09'	System	06 Aug 2020 21:09:47

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 16:08'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 2'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:10:53', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cd17d625-0f29-40e0-89c1-5cf3a38a1b2b'	System	07 Aug 2020 17:11:20
User entered 'None (1)'	System	07 Aug 2020 17:11:20

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:10:57', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cd17d625-0f29-40e0-89c1-5cf3a38a1b2b'	System	07 Aug 2020 17:11:20
User entered 'No (N)'	System	07 Aug 2020 17:11:20

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US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cd17d625-0f29-40e0-89c1-5cf3a38a1b2b'	System	07 Aug 2020 17:11:20
User entered 'No (N)'	System	07 Aug 2020 17:11:20

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:15', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cd17d625-0f29-40e0-89c1-5cf3a38a1b2b'	System	07 Aug 2020 17:11:20
User entered 'None (1)'	System	07 Aug 2020 17:11:20

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:18', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cd17d625-0f29-40e0-89c1-5cf3a38a1b2b'	System	07 Aug 2020 17:11:20
User entered '07 Aug 2020 12:11'	System	07 Aug 2020 17:11:20

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 3'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:33', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cc5a6270-e9f2-45d4-9212-25bdacc645df'	System	09 Aug 2020 02:40:51
User entered 'None (1)'	System	09 Aug 2020 02:40:51

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:07:04
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:36', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cc5a6270-e9f2-45d4-9212-25bdacc645df'	System	09 Aug 2020 02:40:51
User entered 'No (N)'	System	09 Aug 2020 02:40:51

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:39', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cc5a6270-e9f2-45d4-9212-25bdacc645df'	System	09 Aug 2020 02:40:51
User entered 'No (N)'	System	09 Aug 2020 02:40:51

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:43', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cc5a6270-e9f2-45d4-9212-25bdacc645df'	System	09 Aug 2020 02:40:51
User entered 'None (1)'	System	09 Aug 2020 02:40:51

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cc5a6270-e9f2-45d4-9212-25bdacc645df'	System	09 Aug 2020 02:40:51
User entered '08 Aug 2020 21:40'	System	09 Aug 2020 02:40:51

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 4'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:07:04

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:05:42', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6bd609b6-dd8f-4f78-82c6-ba66e77ac467'	System	09 Aug 2020 23:05:58
User entered 'None (1)'	System	09 Aug 2020 23:05:58

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:05:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6bd609b6-dd8f-4f78-82c6-ba66e77ac467'	System	09 Aug 2020 23:05:58
User entered 'No (N)'	System	09 Aug 2020 23:05:58

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:05:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6bd609b6-dd8f-4f78-82c6-ba66e77ac467'	System	09 Aug 2020 23:05:58
User entered 'No (N)'	System	09 Aug 2020 23:05:58

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:05:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6bd609b6-dd8f-4f78-82c6-ba66e77ac467'	System	09 Aug 2020 23:05:58
User entered 'None (1)'	System	09 Aug 2020 23:05:58

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:05:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6bd609b6-dd8f-4f78-82c6-ba66e77ac467'	System	09 Aug 2020 23:05:58
User entered '09 Aug 2020 18:05'	System	09 Aug 2020 23:05:58

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 5'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:03:59', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1b816a9d-c30a-472e-9cff-2ff561c1432e'	System	10 Aug 2020 23:04:13
User entered 'None (1)'	System	10 Aug 2020 23:04:13

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:04:02', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1b816a9d-c30a-472e-9cff-2ff561c1432e'	System	10 Aug 2020 23:04:13
User entered 'No (N)'	System	10 Aug 2020 23:04:13

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:04:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1b816a9d-c30a-472e-9cff-2ff561c1432e'	System	10 Aug 2020 23:04:13
User entered 'No (N)'	System	10 Aug 2020 23:04:13

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:04:06', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1b816a9d-c30a-472e-9cff-2ff561c1432e'	System	10 Aug 2020 23:04:13
User entered 'None (1)'	System	10 Aug 2020 23:04:13

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:04:09', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1b816a9d-c30a-472e-9cff-2ff561c1432e'	System	10 Aug 2020 23:04:13
User entered '10 Aug 2020 18:04'	System	10 Aug 2020 23:04:13

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 6'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:23', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '98f56990-75c7-4b4d-8610-faf64ba201ca'	System	11 Aug 2020 22:51:38
User entered 'None (1)'	System	11 Aug 2020 22:51:38

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:26', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '98f56990-75c7-4b4d-8610-faf64ba201ca'	System	11 Aug 2020 22:51:38
User entered 'No (N)'	System	11 Aug 2020 22:51:38

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:28', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '98f56990-75c7-4b4d-8610-faf64ba201ca'	System	11 Aug 2020 22:51:38
User entered 'No (N)'	System	11 Aug 2020 22:51:38

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:30', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '98f56990-75c7-4b4d-8610-faf64ba201ca'	System	11 Aug 2020 22:51:38
User entered 'None (1)'	System	11 Aug 2020 22:51:38

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:32', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '98f56990-75c7-4b4d-8610-faf64ba201ca'	System	11 Aug 2020 22:51:38
User entered '11 Aug 2020 17:51'	System	11 Aug 2020 22:51:38

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 7'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:07:04

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:38', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5806aa2a-d8d9-4fbc-b94f-fdeb016800fd'	System	12 Aug 2020 23:17:52
User entered 'None (1)'	System	12 Aug 2020 23:17:52

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:41', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5806aa2a-d8d9-4fbc-b94f-fdeb016800fd'	System	12 Aug 2020 23:17:52
User entered 'No (N)'	System	12 Aug 2020 23:17:52

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:43', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5806aa2a-d8d9-4fbc-b94f-fdeb016800fd'	System	12 Aug 2020 23:17:52
User entered 'No (N)'	System	12 Aug 2020 23:17:52

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:07:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5806aa2a-d8d9-4fbc-b94f-fdeb016800fd'	System	12 Aug 2020 23:17:52
User entered 'None (1)'	System	12 Aug 2020 23:17:52

US3212066

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5806aa2a-d8d9-4fbc-b94f-fdeb016800fd'	System	12 Aug 2020 23:17:52
User entered '12 Aug 2020 18:17'	System	12 Aug 2020 23:17:52

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:06', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:10', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:18', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'None (0)'	System	06 Aug 2020 17:53:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:23', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered 'No (N)'	System	06 Aug 2020 17:53:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T12:53:25', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '33feaf69-51f7-4364-a019-b02ecddce9e5'	System	06 Aug 2020 17:53:29
User entered '06 Aug 2020 12:53'	System	06 Aug 2020 17:53:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 12:43'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 15:13'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:10', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:17', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:19', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'None (0)'	System	06 Aug 2020 22:50:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:21', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered 'No (N)'	System	06 Aug 2020 22:50:29

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-06T17:50:24', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b484cc51-1275-47e6-9d43-1b2443d6e71b'	System	06 Aug 2020 22:50:29
User entered '06 Aug 2020 17:50'	System	06 Aug 2020 22:50:29

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '06 Aug 2020 16:08'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 2'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:31', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'None (0)'	System	07 Aug 2020 17:12:26

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:36', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'Some interference with activity (2)'	System	07 Aug 2020 17:12:26

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:07:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:40', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'None (0)'	System	07 Aug 2020 17:12:26

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:11:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'None (0)'	System	07 Aug 2020 17:12:26

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:12:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	07 Aug 2020 17:12:26

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:12:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'No interference with activity (1)'	System	07 Aug 2020 17:12:26

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:12:19', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered 'No (N)'	System	07 Aug 2020 17:12:26

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-07T12:12:22', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e308d433-9d11-46b7-a993-c760b95f4409'	System	07 Aug 2020 17:12:26
User entered '07 Aug 2020 12:12'	System	07 Aug 2020 17:12:26

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 3'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'No interference with activity (1)'	System	09 Aug 2020 02:41:20

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'No interference with activity (1)'	System	09 Aug 2020 02:41:20

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:07:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:40:58', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'None (0)'	System	09 Aug 2020 02:41:20

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:41:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'None (0)'	System	09 Aug 2020 02:41:20

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:07:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:41:08', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 02:41:20

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:41:11', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'None (0)'	System	09 Aug 2020 02:41:20

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:41:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered 'No (N)'	System	09 Aug 2020 02:41:20

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-08T21:41:17', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eba3dc18-7449-4782-af2c-25973c70c297'	System	09 Aug 2020 02:41:20
User entered '08 Aug 2020 21:41'	System	09 Aug 2020 02:41:20

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 4'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:02', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:09', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'Significant; prevents daily activity (3)'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:13', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'Some interference with activity (2)'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:20', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'None (0)'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:27', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:32', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	09 Aug 2020 23:06:54

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered 'No (N)'	System	09 Aug 2020 23:06:54

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-09T18:06:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1a2ec58a-159d-4ca9-9f40-f39a732be482'	System	09 Aug 2020 23:06:54
User entered '09 Aug 2020 18:06'	System	09 Aug 2020 23:06:54

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 5'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:06:21

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:05:58', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'Some interference with activity (2)'	System	10 Aug 2020 23:06:21

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:07:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:01', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'None (0)'	System	10 Aug 2020 23:06:21

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:07:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'None (0)'	System	10 Aug 2020 23:06:21

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:08', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 23:06:21

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:12', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:06:21

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:15', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered 'No (N)'	System	10 Aug 2020 23:06:21

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-10T18:06:17', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '1e9c2658-2a9e-4fb9-8e37-f1c27553e64e'	System	10 Aug 2020 23:06:21
User entered '10 Aug 2020 18:06'	System	10 Aug 2020 23:06:21

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 6'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:40', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'None (0)'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'Some interference with activity (2)'	System	11 Aug 2020 22:52:09

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:07:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'None (0)'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'None (0)'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Aug 2020 22:52:09

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:07:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:51:58', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'None (0)'	System	11 Aug 2020 22:52:09

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:52:01', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered 'No (N)'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-11T17:52:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '70818522-c61d-4003-bdba-9c588a7f09af'	System	11 Aug 2020 22:52:09
User entered '11 Aug 2020 17:52'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 7'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'None (0)'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:18', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'No interference with activity (1)'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:21', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'None (0)'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:23', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'None (0)'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:27', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:07:04
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:29', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'None (0)'	System	12 Aug 2020 23:17:38

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:31', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered 'No (N)'	System	12 Aug 2020 23:17:38

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-12T18:17:34', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '22171f53-4053-4a1a-a19a-92886f716aa4'	System	12 Aug 2020 23:17:38
User entered '12 Aug 2020 18:17'	System	12 Aug 2020 23:17:38

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:24:12

US3212066

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	11 Aug 2020 22:52:09
User entered 'Day 8'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:37', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '88e86168-483a-4d98-a6a0-aa320856cac6'	System	14 Aug 2020 11:26:45
User entered 'No interference with activity (1)'	System	14 Aug 2020 11:26:45

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:40', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '88e86168-483a-4d98-a6a0-aa320856cac6'	System	14 Aug 2020 11:26:45
User entered '14 Aug 2020 06:26'	System	14 Aug 2020 11:26:45

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:52:09

Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	12 Aug 2020 23:17:38
User entered 'Day 9'	System	12 Aug 2020 23:17:38

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:07:04

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T12:09:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'dc424088-1ae6-4c4d-b130-897c51422952'	System	14 Aug 2020 17:09:11
User entered 'Some interference with activity (2)'	System	14 Aug 2020 17:09:11

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T12:09:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'dc424088-1ae6-4c4d-b130-897c51422952'	System	14 Aug 2020 17:09:11
User entered '14 Aug 2020 12:09'	System	14 Aug 2020 17:09:11

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(9)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 23:17:38

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 23:17:38

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	14 Aug 2020 11:26:45
User entered 'Day 10'	System	14 Aug 2020 11:26:45

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 22:07:04

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T07:04:48', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b57eb3b8-fb7f-4e0c-946f-c60b9d4b9c7e'	System	16 Aug 2020 12:04:52
User entered 'No interference with activity (1)'	System	16 Aug 2020 12:04:52

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T07:04:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'b57eb3b8-fb7f-4e0c-946f-c60b9d4b9c7e'	System	16 Aug 2020 12:04:52
User entered '16 Aug 2020 07:04'	System	16 Aug 2020 12:04:52

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(10)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 11:26:45

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 11:26:45

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	14 Aug 2020 17:09:11
User entered 'Day 11'	System	14 Aug 2020 17:09:11

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 22:07:04

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T13:32:29', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e65847a0-6feb-43f3-8a85-bcc7e7020f82'	System	16 Aug 2020 18:32:34
User entered 'None (0)'	System	16 Aug 2020 18:32:34

US3212066

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:07:04

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T13:32:31', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e65847a0-6feb-43f3-8a85-bcc7e7020f82'	System	16 Aug 2020 18:32:34
User entered '16 Aug 2020 13:32'	System	16 Aug 2020 18:32:34

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:09:11

US3212066
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(11)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:09:11

US3212066
Folder: Diary Dose 1 (1)
Form: Nausea_Day(8)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	11 Aug 2020 22:52:09
User entered 'Day 8'	System	11 Aug 2020 22:52:09

US3212066

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:07:04

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '4d2381a7-1ed3-457e-9e49-7531bff8d5a0'	System	14 Aug 2020 11:26:57
User entered 'None (0)'	System	14 Aug 2020 11:26:57

US3212066
Folder: Diary Dose 1 (1)
Form: Nausea_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '4d2381a7-1ed3-457e-9e49-7531bff8d5a0'	System	14 Aug 2020 11:26:57
User entered '14 Aug 2020 06:26'	System	14 Aug 2020 11:26:57

US3212066
Folder: Diary Dose 1 (1)
Form: Nausea_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: Nausea_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:52:09

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	11 Aug 2020 22:51:26
User entered 'Day 8'	System	11 Aug 2020 22:51:26

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5840e52-4f0f-495f-8753-97a8797f1752'	System	14 Aug 2020 11:27:03
User entered 'No (N)'	System	14 Aug 2020 11:27:03

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:07:04
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-14T06:26:58', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f5840e52-4f0f-495f-8753-97a8797f1752'	System	14 Aug 2020 11:27:03
User entered '14 Aug 2020 06:26'	System	14 Aug 2020 11:27:03

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:07:04

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:51:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:51:26

FDA-CBER-2022-1614-0616907

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	14 Aug 2020 11:26:45
User entered 'Day 10'	System	14 Aug 2020 11:26:45

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T07:04:54', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7e0ff075-5134-4192-82e8-35ee837afd16'	System	16 Aug 2020 12:04:58
User entered 'No (N)'	System	16 Aug 2020 12:04:58

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T07:04:56', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7e0ff075-5134-4192-82e8-35ee837afd16'	System	16 Aug 2020 12:04:58
User entered '16 Aug 2020 07:04'	System	16 Aug 2020 12:04:58

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 11:26:45

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 11:26:45

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	14 Aug 2020 17:09:11
User entered 'Day 11'	System	14 Aug 2020 17:09:11

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T13:32:34', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a716a432-9843-472e-b139-97bffea87ae9'	System	16 Aug 2020 18:32:38
User entered 'No (N)'	System	16 Aug 2020 18:32:38

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:07:04

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-08-16T13:32:36', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a716a432-9843-472e-b139-97bffea87ae9'	System	16 Aug 2020 18:32:38
User entered '16 Aug 2020 13:32'	System	16 Aug 2020 18:32:38

US3212066
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 11 Aug 2021 22:07:04
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:09:11

US3212066

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:07:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:09:11

US3212066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:40:07

US3212066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:40:07

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:40:07

US3212066

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Participant is in illness visit/convalescent period'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:40:07

US3212066

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:39:38

US3212066
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	18 Aug 2020 20:39:38

US3212066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	07 Oct 2020 17:38:22

US3212066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	07 Oct 2020 17:38:22

US3212066

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	07 Oct 2020 17:38:22

US3212066
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	07 Oct 2020 17:38:22

US3212066

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:44:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	03 Sep 2020 16:44:36

US3212066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:15:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '27 Aug 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:15:06

US3212066

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:15:06

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 15:15:06

US3212066

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:44:42

US3212066
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	03 Sep 2020 16:44:42

US3212066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:45:43

US3212066
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:14:33
User entered '3 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:45:43

US3212066

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:45:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'VISIT2'	System	03 Sep 2020 16:45:43

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:14:28
User entered '3 Sep 2020'	Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '09:33'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

FDA-CBER-2022-1614-0616943

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '03 Sep 2020 09:33'	System	04 Dec 2020 16:14:28
User entered '3 Sep 2020 09:33'	System	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '97.5' F	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '85'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'bpm'	System	11 Sep 2020 14:06:30

FDA-CBER-2022-1614-0616949

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '16'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'breaths/min'	System	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '109'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '65'	(b) (4) Laura Ngansop Djampou (b) (4)	11 Sep 2020 14:06:30

US3212066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered 'mmHg'	System	11 Sep 2020 14:06:30

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	09 Oct 2020 16:33:51

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

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US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	09 Oct 2020 16:33:51

US3212066

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:45:56

US3212066

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 21:40:12
User entered '3 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:45:56

US3212066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:09

US3212066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:09

US3212066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:09

US3212066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	03 Sep 2020 16:46:09

US3212066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:09

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:09

US3212066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	03 Sep 2020 16:46:09

US3212066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4)　(b) (4)　(b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4)　(b) (4)	03 Sep 2020 16:46:09

US3212066
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	03 Sep 2020 16:46:09

US3212066

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	03 Sep 2020 16:46:09

US3212066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:38

US3212066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:14:44
User entered '3 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:38

US3212066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '10:49'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:38

US3212066

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '03 Sep 2020 10:49'	System	04 Dec 2020 16:14:44
User entered '3 Sep 2020 10:49'	System	03 Sep 2020 16:46:38

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '03 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 21:40:28
User entered '3 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

US3212066
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:07:04
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '10:44'	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '03 Sep 2020 10:44'	System	04 Dec 2020 21:40:28
User entered '3 Sep 2020 10:44'	System	03 Sep 2020 16:46:48

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:07:04

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:48

FDA-CBER-2022-1614-0616995

US3212066

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered empty.	System	03 Sep 2020 16:46:48

US3212066

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:01
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 16:46:53

US3212066
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	14 Sep 2020 16:04:01
User entered empty.	System	03 Sep 2020 16:46:53

US3212066
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '10 Sep 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:16

FDA-CBER-2022-1614-0617000

US3212066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:16

US3212066

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:16

US3212066

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:04:22

US3212066
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	14 Sep 2020 16:04:22

US3212066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 14:13:55

US3212066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '17 Sep 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 14:13:55

US3212066

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 14:13:55

US3212066
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:03:51
	(b) (4)	
	(b) (4)	
User entered empty.	Laura Ngansop Djampou	18 Sep 2020 14:13:55
	(b) (4)	

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 14:14:00

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US3212066
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	18 Sep 2020 14:14:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Sep 2020 15:33:20

US3212066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '24 Sep 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Sep 2020 15:33:20

US3212066

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Sep 2020 15:33:20

US3212066
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Sep 2020 15:33:20

US3212066

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
	(b) (4)	
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Sep 2020 15:33:27

US3212066
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	25 Sep 2020 15:33:27

US3212066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:59

US3212066

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '08 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:14:59
User entered '8 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:59

Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:59

FDA-CBER-2022-1614-0617019

US3212066
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered 'VISIT3'	System	08 Oct 2020 15:41:59

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '08 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:06
User entered '8 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '09:12'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered '08 Oct 2020 09:12'	System	04 Dec 2020 16:15:06
User entered '8 Oct 2020 09:12'	System	08 Oct 2020 15:42:45

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '97.3' F	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:04:00
User entered empty.	(b) (4) Laura Ngansop Djampou	08 Oct 2020 15:42:45

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '81'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered 'bpm'	System	08 Oct 2020 15:42:45

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '18'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

FDA-CBER-2022-1614-0617030

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered 'breaths/min'	System	08 Oct 2020 15:42:45

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '108'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered 'mmHg'	System	08 Oct 2020 15:42:45

FDA-CBER-2022-1614-0617033

US3212066

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '69'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05
User entered 'mmHg'	System	08 Oct 2020 15:42:45

FDA-CBER-2022-1614-0617035

US3212066
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:05

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:55

US3212066

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '08 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:14
User entered '8 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:42:55

US3212066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:39

US3212066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '08 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:21
User entered '8 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:39

US3212066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered '09:45'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:39

US3212066

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '08 Oct 2020 09:45'	System	04 Dec 2020 16:15:21
User entered '8 Oct 2020 09:45'	System	08 Oct 2020 15:41:39

Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:04:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 15:41:47

US3212066
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	08 Oct 2020 15:41:47

US3212066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 64'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-06T11:42:41', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5808cd86-54e2-4fd7-a028-280219750ec6'	System	06 Oct 2020 16:44:05
User entered 'No (N)'	System	06 Oct 2020 16:44:05

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-06T11:43:53', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5808cd86-54e2-4fd7-a028-280219750ec6'	System	06 Oct 2020 16:44:05
User entered 'No (N)'	System	06 Oct 2020 16:44:05

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-06T11:44:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5808cd86-54e2-4fd7-a028-280219750ec6'	System	06 Oct 2020 16:44:05
User entered '06 Oct 2020 11:44:00'	System	06 Oct 2020 16:44:05

US3212066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 71'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-13T16:53:41', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a7f2ce35-a088-431c-a20c-d00fa81533d5'	System	13 Oct 2020 21:53:49
User entered 'No (N)'	System	13 Oct 2020 21:53:49

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-13T16:53:37', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a7f2ce35-a088-431c-a20c-d00fa81533d5'	System	13 Oct 2020 21:53:49
User entered 'No (N)'	System	13 Oct 2020 21:53:49

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-13T16:53:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a7f2ce35-a088-431c-a20c-d00fa81533d5'	System	13 Oct 2020 21:53:49
User entered '13 Oct 2020 16:53:46'	System	13 Oct 2020 21:53:49

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 78'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-20T04:52:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd46df7c8-5353-45cf-a612-81d42b50d51d'	System	20 Oct 2020 09:52:55
User entered 'No (N)'	System	20 Oct 2020 09:52:55

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-20T04:52:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd46df7c8-5353-45cf-a612-81d42b50d51d'	System	20 Oct 2020 09:52:55
User entered 'No (N)'	System	20 Oct 2020 09:52:55

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-10-20T04:52:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd46df7c8-5353-45cf-a612-81d42b50d51d'	System	20 Oct 2020 09:52:55
User entered '20 Oct 2020 04:52:52'	System	20 Oct 2020 09:52:55

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 92'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-03T17:27:38', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd05d9988-a6ee-4d46-bab6-66d4de4e75d8'	System	03 Nov 2020 23:28:09
User entered 'No (N)'	System	03 Nov 2020 23:28:09

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-03T17:28:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd05d9988-a6ee-4d46-bab6-66d4de4e75d8'	System	03 Nov 2020 23:28:09
User entered 'No (N)'	System	03 Nov 2020 23:28:09

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-03T17:28:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'd05d9988-a6ee-4d46-bab6-66d4de4e75d8'	System	03 Nov 2020 23:28:09
User entered '03 Nov 2020 17:28:07'	System	03 Nov 2020 23:28:09

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 99'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-10T04:52:46', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e8b23063-5c13-461b-8895-8a827f7e4a2e'	System	10 Nov 2020 10:53:00
User entered 'No (N)'	System	10 Nov 2020 10:53:00

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-10T04:52:54', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e8b23063-5c13-461b-8895-8a827f7e4a2e'	System	10 Nov 2020 10:53:00
User entered 'No (N)'	System	10 Nov 2020 10:53:00

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-10T04:52:58', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'e8b23063-5c13-461b-8895-8a827f7e4a2e'	System	10 Nov 2020 10:53:00
User entered '10 Nov 2020 04:52:58'	System	10 Nov 2020 10:53:00

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered 'Day 106'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-17T18:29:31', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8c46e669-116f-44c2-9534-282ec6a19d2f'	System	18 Nov 2020 00:29:47
User entered 'No (N)'	System	18 Nov 2020 00:29:47

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-17T18:29:38', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8c46e669-116f-44c2-9534-282ec6a19d2f'	System	18 Nov 2020 00:29:47
User entered 'No (N)'	System	18 Nov 2020 00:29:47

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-17T18:29:41', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8c46e669-116f-44c2-9534-282ec6a19d2f'	System	18 Nov 2020 00:29:47
User entered '17 Nov 2020 18:29:41'	System	18 Nov 2020 00:29:47

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:24:12

US3212066

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:03:16
Data entry locked.	System	06 Aug 2020 17:24:12
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:24:12

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-11-23T18:06:29', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a88b5a75-470d-443f-b792-81f7334ec18a'	System	24 Nov 2020 00:06:39
User entered 'No (N)'	System	24 Nov 2020 00:06:39

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-11-23T18:06:33', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a88b5a75-470d-443f-b792-81f7334ec18a'	System	24 Nov 2020 00:06:39
User entered 'No (N)'	System	24 Nov 2020 00:06:39

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-23T18:06:36', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'a88b5a75-470d-443f-b792-81f7334ec18a'	System	24 Nov 2020 00:06:39
User entered '23 Nov 2020 18:06:36'	System	24 Nov 2020 00:06:39

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-11-30T11:03:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3ac44c9d-6231-461d-94cf-b39ed992ebd0'	System	30 Nov 2020 17:03:23
User entered 'No (N)'	System	30 Nov 2020 17:03:23

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-11-30T11:03:16', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3ac44c9d-6231-461d-94cf-b39ed992ebd0'	System	30 Nov 2020 17:03:23
User entered 'No (N)'	System	30 Nov 2020 17:03:23

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-11-30T11:03:20', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3ac44c9d-6231-461d-94cf-b39ed992ebd0'	System	30 Nov 2020 17:03:23
User entered '30 Nov 2020 11:03:20'	System	30 Nov 2020 17:03:23

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-12-08T10:02:11', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '2dd03bb9-72a3-4d8d-9f7f-c64e46c68e82'	System	08 Dec 2020 16:02:22
User entered 'No (N)'	System	08 Dec 2020 16:02:22

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-12-08T10:02:15', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '2dd03bb9-72a3-4d8d-9f7f-c64e46c68e82'	System	08 Dec 2020 16:02:22
User entered 'No (N)'	System	08 Dec 2020 16:02:22

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-08T10:02:18', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '2dd03bb9-72a3-4d8d-9f7f-c64e46c68e82'	System	08 Dec 2020 16:02:22
User entered '08 Dec 2020 10:02:18'	System	08 Dec 2020 16:02:22

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-12-12T05:15:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cf9330bc-61ce-4209-a6dc-739abf5e99e3'	System	12 Dec 2020 11:15:12
User entered 'No (N)'	System	12 Dec 2020 11:15:12

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-12-12T05:15:06', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cf9330bc-61ce-4209-a6dc-739abf5e99e3'	System	12 Dec 2020 11:15:12
User entered 'No (N)'	System	12 Dec 2020 11:15:12

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-12T05:15:09', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cf9330bc-61ce-4209-a6dc-739abf5e99e3'	System	12 Dec 2020 11:15:12
User entered '12 Dec 2020 05:15:09'	System	12 Dec 2020 11:15:12

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-12-19T06:43:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '27c14ddc-8e5e-4b15-8755-2599aed82292'	System	19 Dec 2020 12:43:53
User entered 'No (N)'	System	19 Dec 2020 12:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-12-19T06:43:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '27c14ddc-8e5e-4b15-8755-2599aed82292'	System	19 Dec 2020 12:43:53
User entered 'No (N)'	System	19 Dec 2020 12:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-19T06:43:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '27c14ddc-8e5e-4b15-8755-2599aed82292'	System	19 Dec 2020 12:43:53
User entered '19 Dec 2020 06:43:50'	System	19 Dec 2020 12:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2020-12-26T09:23:11', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered 'Yes (Y)'	System	26 Dec 2020 15:23:56

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2020-12-26T09:23:14', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered 'No (N)'	System	26 Dec 2020 15:23:56

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-26T09:23:18', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered 'No (N)'	System	26 Dec 2020 15:23:56

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-26T09:23:32', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered 'Yes (Y)'	System	26 Dec 2020 15:23:56

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-26T09:23:42', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 15:23:56

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2020-12-26T09:23:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5150f811-2b2e-4635-93a3-b11140f328bb'	System	26 Dec 2020 15:23:56
User entered '26 Dec 2020 09:23:45'	System	26 Dec 2020 15:23:56

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-01-06T08:31:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8fde71a6-310d-49f3-b8fd-6a3bb94a3b3c'	System	06 Jan 2021 14:31:58
User entered 'No (N)'	System	06 Jan 2021 14:31:58

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-01-06T08:31:51', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8fde71a6-310d-49f3-b8fd-6a3bb94a3b3c'	System	06 Jan 2021 14:31:58
User entered 'No (N)'	System	06 Jan 2021 14:31:58

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-01-06T08:31:53', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '8fde71a6-310d-49f3-b8fd-6a3bb94a3b3c'	System	06 Jan 2021 14:31:58
User entered '06 Jan 2021 08:31:53'	System	06 Jan 2021 14:31:58

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-01-09T07:08:44', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0f39a5b9-a457-400c-a002-7bb672e43e2f'	System	09 Jan 2021 13:08:57
User entered 'No (N)'	System	09 Jan 2021 13:08:57

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-01-09T07:08:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0f39a5b9-a457-400c-a002-7bb672e43e2f'	System	09 Jan 2021 13:08:57
User entered 'No (N)'	System	09 Jan 2021 13:08:57

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-01-09T07:08:50', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '0f39a5b9-a457-400c-a002-7bb672e43e2f'	System	09 Jan 2021 13:08:57
User entered '09 Jan 2021 07:08:50'	System	09 Jan 2021 13:08:57

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-01-16T07:13:56', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5f44c43b-4a3e-4b9e-9017-632f7bfe18a5'	System	16 Jan 2021 13:14:11
User entered 'No (N)'	System	16 Jan 2021 13:14:11

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-01-16T07:14:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5f44c43b-4a3e-4b9e-9017-632f7bfe18a5'	System	16 Jan 2021 13:14:11
User entered 'No (N)'	System	16 Jan 2021 13:14:11

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-01-16T07:14:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '5f44c43b-4a3e-4b9e-9017-632f7bfe18a5'	System	16 Jan 2021 13:14:11
User entered '16 Jan 2021 07:14:07'	System	16 Jan 2021 13:14:11

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:43:53

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-01-27T10:45:03', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'ab9a9752-6504-4fce-9bc8-9c9c24871753'	System	27 Jan 2021 16:45:11
User entered 'No (N)'	System	27 Jan 2021 16:45:11

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-01-27T10:45:04', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'ab9a9752-6504-4fce-9bc8-9c9c24871753'	System	27 Jan 2021 16:45:11
User entered 'No (N)'	System	27 Jan 2021 16:45:11

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-01-27T10:45:07', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'ab9a9752-6504-4fce-9bc8-9c9c24871753'	System	27 Jan 2021 16:45:11
User entered '27 Jan 2021 10:45:07'	System	27 Jan 2021 16:45:11

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-01-30T06:29:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c7218b58-9356-4be8-bf2d-6626108ab009'	System	30 Jan 2021 12:29:58
User entered 'No (N)'	System	30 Jan 2021 12:29:58

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-01-30T06:29:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c7218b58-9356-4be8-bf2d-6626108ab009'	System	30 Jan 2021 12:29:58
User entered 'No (N)'	System	30 Jan 2021 12:29:58

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-01-30T06:29:55', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c7218b58-9356-4be8-bf2d-6626108ab009'	System	30 Jan 2021 12:29:58
User entered '30 Jan 2021 06:29:55'	System	30 Jan 2021 12:29:58

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-02-06T05:44:35', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6725f422-9814-4443-9764-7700a296135f'	System	06 Feb 2021 11:44:51
User entered 'No (N)'	System	06 Feb 2021 11:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-02-06T05:44:47', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6725f422-9814-4443-9764-7700a296135f'	System	06 Feb 2021 11:44:51
User entered 'No (N)'	System	06 Feb 2021 11:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-06T05:44:49', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '6725f422-9814-4443-9764-7700a296135f'	System	06 Feb 2021 11:44:51
User entered '06 Feb 2021 05:44:49'	System	06 Feb 2021 11:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:43:53

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US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-02-13T08:08:45', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cdd47a94-cd0e-4ef4-a8e3-a18bdc3d56bf'	System	13 Feb 2021 14:08:55
User entered 'No (N)'	System	13 Feb 2021 14:08:55

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-02-13T08:08:48', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cdd47a94-cd0e-4ef4-a8e3-a18bdc3d56bf'	System	13 Feb 2021 14:08:55
User entered 'No (N)'	System	13 Feb 2021 14:08:55

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-13T08:08:52', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'cdd47a94-cd0e-4ef4-a8e3-a18bdc3d56bf'	System	13 Feb 2021 14:08:55
User entered '13 Feb 2021 08:08:52'	System	13 Feb 2021 14:08:55

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-02-24T16:50:05-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7d18373f-fccf-409f-b352-f560d503d474'	System	24 Feb 2021 23:03:42
User entered 'No (N)'	System	24 Feb 2021 23:03:42

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-02-24T16:50:07-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7d18373f-fccf-409f-b352-f560d503d474'	System	24 Feb 2021 23:03:42
User entered 'No (N)'	System	24 Feb 2021 23:03:42

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-24T16:50:12-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '7d18373f-fccf-409f-b352-f560d503d474'	System	24 Feb 2021 23:03:42
User entered '24 Feb 2021 16:50:12'	System	24 Feb 2021 23:03:42

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (dc355823aca6a4fd)', Time: '2021-02-27T05:35:13-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '76ebbf6a-2bc3-4b5e-889a-5baee584f710'	System	27 Feb 2021 11:35:25
User entered 'No (N)'	System	27 Feb 2021 11:35:25

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (dc355823aca6a4fd)', Time: '2021-02-27T05:35:19-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '76ebbf6a-2bc3-4b5e-889a-5baee584f710'	System	27 Feb 2021 11:35:25
User entered 'No (N)'	System	27 Feb 2021 11:35:25

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-27T05:35:21-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '76ebbf6a-2bc3-4b5e-889a-5baee584f710'	System	27 Feb 2021 11:35:25
User entered '27 Feb 2021 05:35:21'	System	27 Feb 2021 11:35:25

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-03-17T08:44:41-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '4803e094-a880-430f-a41a-78dc1ec918de'	System	17 Mar 2021 13:44:51
User entered 'No (N)'	System	17 Mar 2021 13:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-03-17T08:44:43-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '4803e094-a880-430f-a41a-78dc1ec918de'	System	17 Mar 2021 13:44:51
User entered 'No (N)'	System	17 Mar 2021 13:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-03-17T08:44:47-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '4803e094-a880-430f-a41a-78dc1ec918de'	System	17 Mar 2021 13:44:51
User entered '17 Mar 2021 08:44:47'	System	17 Mar 2021 13:44:51

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-03-24T08:42:41-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f40ed8b6-e4bf-4bb8-b646-d71edf97b108'	System	24 Mar 2021 13:42:49
User entered 'No (N)'	System	24 Mar 2021 13:42:49

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-03-24T08:42:43-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f40ed8b6-e4bf-4bb8-b646-d71edf97b108'	System	24 Mar 2021 13:42:49
User entered 'No (N)'	System	24 Mar 2021 13:42:49

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-03-24T08:42:45-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'f40ed8b6-e4bf-4bb8-b646-d71edf97b108'	System	24 Mar 2021 13:42:49
User entered '24 Mar 2021 08:42:45'	System	24 Mar 2021 13:42:49

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-03-29T21:30:54-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c0afe032-caab-45e8-b08d-fdb31b6abbc1'	System	30 Mar 2021 02:31:06
User entered 'No (N)'	System	30 Mar 2021 02:31:06

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-03-29T21:30:56-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c0afe032-caab-45e8-b08d-fdb31b6abbc1'	System	30 Mar 2021 02:31:06
User entered 'No (N)'	System	30 Mar 2021 02:31:06

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-03-29T21:30:58-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'c0afe032-caab-45e8-b08d-fdb31b6abbc1'	System	30 Mar 2021 02:31:06
User entered '29 Mar 2021 21:30:58'	System	30 Mar 2021 02:31:06

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-04-07T08:36:03-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3dae94b3-82a7-4d25-8925-26c94ceb98c3'	System	07 Apr 2021 13:36:12
User entered 'No (N)'	System	07 Apr 2021 13:36:12

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-04-07T08:36:04-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3dae94b3-82a7-4d25-8925-26c94ceb98c3'	System	07 Apr 2021 13:36:12
User entered 'No (N)'	System	07 Apr 2021 13:36:12

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-04-07T08:36:06-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '3dae94b3-82a7-4d25-8925-26c94ceb98c3'	System	07 Apr 2021 13:36:12
User entered '07 Apr 2021 08:36:06'	System	07 Apr 2021 13:36:12

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-04-14T08:33:17-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '488165b1-0d25-4071-8db1-8dc8162bdbf7'	System	14 Apr 2021 16:01:43
User entered 'No (N)'	System	14 Apr 2021 16:01:43

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-04-14T08:33:19-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '488165b1-0d25-4071-8db1-8dc8162bdbf7'	System	14 Apr 2021 16:01:43
User entered 'No (N)'	System	14 Apr 2021 16:01:43

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-04-14T08:33:21-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '488165b1-0d25-4071-8db1-8dc8162bdbf7'	System	14 Apr 2021 16:01:43
User entered '14 Apr 2021 08:33:21'	System	14 Apr 2021 16:01:43

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-04-21T08:37:25-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'faf65a86-78bc-47c8-ada3-e3977dcb66e0'	System	21 Apr 2021 13:37:37
User entered 'No (N)'	System	21 Apr 2021 13:37:37

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-04-21T08:37:27-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'faf65a86-78bc-47c8-ada3-e3977dcb66e0'	System	21 Apr 2021 13:37:37
User entered 'No (N)'	System	21 Apr 2021 13:37:37

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-04-21T08:37:29-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'faf65a86-78bc-47c8-ada3-e3977dcb66e0'	System	21 Apr 2021 13:37:37
User entered '21 Apr 2021 08:37:29'	System	21 Apr 2021 13:37:37

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-04-28T08:35:26-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '9203817d-45ea-469e-8b64-4523129c644e'	System	29 Apr 2021 00:49:30
User entered 'No (N)'	System	29 Apr 2021 00:49:30

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-04-28T08:35:29-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '9203817d-45ea-469e-8b64-4523129c644e'	System	29 Apr 2021 00:49:30
User entered 'No (N)'	System	29 Apr 2021 00:49:30

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-04-28T08:35:31-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '9203817d-45ea-469e-8b64-4523129c644e'	System	29 Apr 2021 00:49:30
User entered '28 Apr 2021 08:35:31'	System	29 Apr 2021 00:49:30

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

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 (ba353dd48d13e938)', Time: '2021-05-02T20:29:58-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '410f306b-b0c1-455d-ac81-0b0b058dc158'	System	03 May 2021 01:30:08
User entered 'No (N)'	System	03 May 2021 01:30:08

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Have you been exposed to someone with 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 (ba353dd48d13e938)', Time: '2021-05-02T20:30:03-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '410f306b-b0c1-455d-ac81-0b0b058dc158'	System	03 May 2021 01:30:08
User entered 'No (N)'	System	03 May 2021 01:30:08

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba353dd48d13e938)', Time: '2021-05-02T20:30:05-05:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: '410f306b-b0c1-455d-ac81-0b0b058dc158'	System	03 May 2021 01:30:08
User entered '02 May 2021 20:30:05'	System	03 May 2021 01:30:08

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:43:53

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:43:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:43:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:43:53

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:43:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:43:53

FDA-CBER-2022-1614-0617417

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:43:53

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:43:53

US3212066

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:07:04

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:43:53

US3212066
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:07:04
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:43:53
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:43:53

US3212066

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:07:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-27T05:35:03-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eb132703-4d05-41e3-a5b5-91fe777d83b1'	System	27 Feb 2021 11:35:10
User entered 'No (N)'	System	27 Feb 2021 11:35:10

US3212066

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:07:04

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc355823aca6a4fd)', Time: '2021-02-27T05:35:07-06:00', User OID: 'PatientReportedOutcome (US3212066)', ODM File OID: 'eb132703-4d05-41e3-a5b5-91fe777d83b1'	System	27 Feb 2021 11:35:10
User entered '27 Feb 2021 05:35:07'	System	27 Feb 2021 11:35:10

US3212066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered '27 Oct 2020' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Feb 2021 22:12:47
User entered '27 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:55

US3212066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:55

US3212066

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:15:55

US3212066

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	26 Mar 2021 18:03:51
	(b) (4)	
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:04

US3212066

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:00:03
User entered '1'	System	04 Dec 2020 16:16:04

US3212066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:27

US3212066

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:27

US3212066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:27

US3212066
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:27

US3212066

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:16:32

US3212066
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '1'	System	04 Dec 2020 16:16:32

US3212066
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:16:09

US3212066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '29 Dec 2020'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:16:09

US3212066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:16:09

US3212066

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Called for safety call, no answer, left voicemail and sent text.'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:16:09

US3212066

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:16:15

US3212066
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '1'	System	30 Dec 2020 15:16:15

US3212066
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:33:34

US3212066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '02 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:33:34

US3212066
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:33:34

US3212066

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:33:34

US3212066

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:33:47

US3212066

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '1'	System	08 Feb 2021 19:33:47

US3212066
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:36:46

US3212066
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:36:46

US3212066

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:36:46

US3212066
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered 'VISIT4'	System	01 Mar 2021 15:36:46

US3212066

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered '12:41'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '26 Feb 2021 12:41'	System	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.0' F	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '79'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered 'bpm'	System	30 Mar 2021 17:18:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '16'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

FDA-CBER-2022-1614-0617490

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered 'breaths/min'	System	30 Mar 2021 17:18:36

FDA-CBER-2022-1614-0617491

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '97'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered 'mmHg'	System	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '74'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 17:18:36

US3212066
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered 'mmHg'	System	30 Mar 2021 17:18:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13

US3212066

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:36:58

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:36:58

US3212066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:16

FDA-CBER-2022-1614-0617501

US3212066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '13:32'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:16

US3212066

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '26 Feb 2021 13:32'	System	01 Mar 2021 15:37:16

US3212066

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:25

US3212066
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:26:13
User entered '1'	System	01 Mar 2021 15:37:25

US3212066
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 16:10:47

US3212066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '31 Mar 2021'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 16:10:47

US3212066

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 16:10:47

US3212066
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 16:10:47

US3212066

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 16:22:26

US3212066
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:00
User entered '1'	System	01 Apr 2021 16:22:26

US3212066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	30 Apr 2021 18:13:11
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 13:57:48

US3212066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	30 Apr 2021 18:13:11
User entered '28 Apr 2021'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 13:57:48

US3212066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	30 Apr 2021 18:13:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 13:57:48

US3212066

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	30 Apr 2021 18:13:11
User entered 'Called subject regarding Day 269 safety call. No answer, voicemail left.'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 13:57:48

US3212066

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	30 Apr 2021 18:13:11
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 13:57:57

US3212066

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:57:57

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:07:04

Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:10
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:51:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:07:04

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:10
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '12:09'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:51:31

Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:10
User entered '04 Jan 2021 12:09'	System	07 Jan 2021 17:51:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:07:04

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:10
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:51:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:07:04

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:10
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:51:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 1 (Day 1)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '24 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered '%'	System	07 Jan 2021 17:54:31

FDA-CBER-2022-1614-0617527

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:31

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '25 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:54:37

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

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New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

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Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:54:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:56:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 17:56:26
User entered '26 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 17:55:02
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:55:02

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '27 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617590

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617602

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617612

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617631

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '29 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617637

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '30 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617669

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 8 (Day 8)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '31 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

FDA-CBER-2022-1614-0617681

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '01 Jan 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37
User entered '01 Jan 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 10 (Day 10)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '02 Jan 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37
User entered '02 Jan 2020'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '1'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:56:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 11 (Day 11)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '03 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered empty.	System	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

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US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

FDA-CBER-2022-1614-0617763

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 12 (Day 12)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '100'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered '%'	System	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

FDA-CBER-2022-1614-0617771

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 17:59:37

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 13 (Day 13)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '05 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '99'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered '%'	System	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.1' F	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

FDA-CBER-2022-1614-0617802

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

FDA-CBER-2022-1614-0617803

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:02:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '06 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered '%'	System	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.4' F	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:03:23

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 15 (Day 15)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '07 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '99'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User entered '%'	System	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.2' F	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

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US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:08

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:45:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession number: 1F63549 this sample is in PPD Lab portal and has even generated a result. The sample has been received. No tracking necessary as the result is clearly in portal. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	22 Jan 2021 18:42:53
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:27:23
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

US3212066
Folder: Covid-19 Assessment 04 Jan 2021
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:07:04
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per CDM: Response noted, please update and respond to query when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 17:28:42
Query 'Per CDM: Response noted, please update and respond to query when data becomes available. Thank you' answered with 'updated ' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:25
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:19
User opened query 'Per CDM: Response noted, please update and respond to query when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 12:12:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 12:12:16
Query 'Data is required. Please complete.' answered with 'ADDING LATER ' (Site from System).	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:31
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 18:01:26
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

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US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

US3212066

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:01:26

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:49:23
User entered '0'	System	08 Jan 2021 15:34:19

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:07:04
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:02:45
User entered '14 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:13:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:07:04

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:02:45
User entered '21:12'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:13:21

Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:25
User entered '14 Aug 2020 21:12'	System	18 Aug 2020 19:13:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:07:04
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:02:45
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:13:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:07:04

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:02:45
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:13:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 1 (Day 1)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:18:57
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '09 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 14:35:49
User entered '14 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered '97.5' F	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 14:13:30
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 14:13:30
User entered 'Mild (Mild)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:19:27
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Moderate (Moderate)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 14:13:30
User entered 'Moderate (Moderate)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 14:13:30
User entered 'Moderate (Moderate)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 14:15:58
User entered 'Mild (Mild)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:23:03

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US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:45:06
User entered '15 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:45:09
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:45:35
User entered '100'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:45:23
User entered '98.4' F	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:45:49
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:00
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:46:53
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:08
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:46:15
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:46:19
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:29
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:46:33
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:35
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:46:41
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:43
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:46:59
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:47:01
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:47:08
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:47:11
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:18:10

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:49:15
User entered '16 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:49:38
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:49:35
User entered '98'	Afifah Ayub (b) (4)	30 Sep 2020 16:41:04
	(b) (4)	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:49:25
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:25
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:30
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Sep 2020 16:41:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:09:20
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:41
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:47
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:49
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:08:56
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:01
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:02
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:07
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:13
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:27
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:30
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:36
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:09:39
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:41:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:03
User entered '17 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12
User entered '17 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:04
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:25
User entered '98'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:11
User entered '97.6' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:35:38
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:47
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:11:51
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:13:36
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:12:02
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:12:07
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:12:10
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:12:55
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:36:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:35:47
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:12:59
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:13:00
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

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Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:13:06
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:13:08
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:13:15
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:13:17
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:13:21
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:13:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:42:22

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:14:53
User entered '18 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:14:54
User entered '0'	Afifah Ayub (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:09
User entered '99'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:03
User entered '98.3' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:36:12
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:19
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:28
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:55:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:35
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:55:26
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:40
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:44
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:15:50
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:01
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:03
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:12
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:14
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:19
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:16:21
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:42:41
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:23
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:16:24
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:49:12

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:27
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	30 Sep 2020 16:52:27

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:28
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:38
User entered '98'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:52:27

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:34
User entered '98.6' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:36:17
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:52
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:01
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:08
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:14
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:15
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:24
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:18:28
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:30
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:34
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:35
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:44
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:18:45
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:45:30
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:50
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:18:51
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:52:27

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:20
User entered '20 Aug 2020'	Afifah Ayub (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:22
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:30
User entered '99'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:40
User entered '98.4' F	Afifah Ayub (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:36:26
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:52
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:57
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:20:09
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:20:11
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:20:14
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:20:16
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:20:24
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:21:34
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:21:36
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 18:47:01
	(b) (4)	
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Sep 2020 16:54:39
	(b) (4)	

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:21:40
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:21:41
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:21:49
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:21:55
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:47:01
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:22:00
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:22:03
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:54:39

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 8 (Day 8)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:22:20
User entered '21 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:22:21
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:22:28
User entered '100'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 16:57:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:23:52
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:24:04
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:07
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:12
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 18:49:51
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:21
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:25
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:34
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:37
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:44
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:52
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:25:00
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:25:40
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:25:50
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:25:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:49:51
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:26:04
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:25:59
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

FDA-CBER-2022-1614-0618042

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:25:35
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:57:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:29:54
User entered '22 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:29:56
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:29:58
User entered '99'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:23
User entered '98.1' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:41
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

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Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:44
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

FDA-CBER-2022-1614-0618051

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:50
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 18:52:03
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:53
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:52:03
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:30:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:03
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:52:03
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:06
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:52:03
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:14
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:21
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:24
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:34
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:52:03
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:40
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:44
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:52:03
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:52
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:31:53
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:32:04
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:01:21

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 10 (Day 10)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:32:29
User entered '23 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:32:31
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:32:39
User entered '99'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:32:42
User entered '98.2' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:04
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:07
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:13
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:18
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:28
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:31
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:38
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:46
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:51
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:33:59
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:34:02
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:34:06
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:53:59
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:34:09
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:34:12
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:34:21
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:03:49

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 12 (Day 12)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:34:41
User entered '25 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:34:42
User entered '0'	Afifah Ayub (b) (4)	30 Sep 2020 17:11:18
	(b) (4)	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:08
User entered '99'	Afifah Ayub (b) (4)	30 Sep 2020 17:11:18
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:32
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:40
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:44
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:49
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:51
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:56
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:00
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:07:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:08
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:36:12
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

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Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:14
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:17
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:32
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:36
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:42
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 18:55:19
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:48
User entered 'None (None)'	Afifah Ayub (b) (4)	30 Sep 2020 17:11:18
	(b) (4)	

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:51
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

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Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:36:24
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:11:18

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04
User entered 'Day 11 (Day 11)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:00
User entered '24 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:02
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:05
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered empty.	System	29 Oct 2020 17:09:38

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:06
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:08
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

FDA-CBER-2022-1614-0618123

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:18
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

FDA-CBER-2022-1614-0618124

Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:20
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:23
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:26
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:27
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:09:38

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:45
User entered '10 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:47
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered empty.	System	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:52
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:55
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:56
User entered empty.	Afifah Ayub (b) (4)	29 Oct 2020 17:11:04
	(b) (4)	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:38:59
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:01
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:03
User entered empty.	Afifah Ayub (b) (4)	29 Oct 2020 17:11:04
	(b) (4)	

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:04
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:05
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:07
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:17
User entered '11 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:18
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:20
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered empty.	System	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:26
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Afifah Ayub (b) (4)	29 Oct 2020 17:11:04
	(b) (4)	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:34
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:36
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:41
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:42
User entered empty.	Afifah Ayub (b) (4)	29 Oct 2020 17:11:04
	(b) (4)	

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:44
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:45
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:49
User entered '12 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:50
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:53
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered empty.	System	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:39:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:59
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:01
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:02
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:03
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:05
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:06
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:07
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:07:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:18
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:21
User entered '13 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:23
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered empty.	System	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:40:27
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:30
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:33
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:37
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:41
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:43
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:45
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:07:04

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:07:04
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:54
User entered '14 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:37:00
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered '0' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:40:58
User entered '1'	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:37:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:01
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
User entered '%'	System	03 Nov 2020 18:00:43
User entered empty.	System	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:22:36
User closed query 'Per source, temp is 98.3. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 18:22:23
Query 'Per source, temp is 98.3. Please verify and update accordingly.' answered with 'Per COVID Day 1 visit in source for 14AUG2020, this stands as correct.' (Site from CRA).	Afifah Ayub (b) (4) (b) (4)	23 Apr 2021 16:36:53
User opened query 'Per source, temp is 98.3. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 13:38:24
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered '97.5' F reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:02
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:38:52
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:04
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:38:57
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:05
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:39:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:07
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:39:19
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:08
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:39:12
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:39:23
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:39:34
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:44:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:45:58
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:04
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:18
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:19
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:10
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:15
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:07:04
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:41:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:07:04

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:32
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:46:19
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Afifah Ayub (b) (4)	03 Nov 2020 18:00:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Afifah Ayub (b) (4) (b) (4)	03 Nov 2020 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:41:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 17:11:04

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:07:04
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:42:37
User entered '14 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:42:39
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:42:48
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:13:02
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE added' (Site from System).	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:12:31
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Aug 2020 19:24:01
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:34:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:24:21
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 17:24:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06AUG2020 under Covid-19 Assessment in EDC, however same is reported as Visit 1 Day 1 in PPD central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 08:47:58
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06AUG2020 under Covid-19 Assessment in EDC, however same is reported as Visit 1 Day 1 in PPD central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'subject received the PCR swab on 06AUG2020 @ V1D1 per protocol. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	08 Feb 2021 19:27:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06AUG2020 under Covid-19 Assessment in EDC, however same is reported as Visit 1 Day 1 in PPD central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:57:45

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Date of Test

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "V1D1 requires a covid 19 test."; however, visit 1 Day 1 swab sample collected on 06-AUG-2020 is correctly entered in EDC. Per PPD portal, swab sample dated 14-AUG-2020 is reported under Illness Visit Day 1 in PPD portal however, swab sample of 14-AUG-2020 is missing in EDC. Kindly review if the swab sample for 14-AUG-2020 was collected, if yes, consider updating date of test as appropriate, also clarify in site response, if 06-AUG-2020 swab sample was collected for visit 1 day 1 or specify the correct visit name.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:35:10
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "V1D1 requires a covid 19 test."; however, visit 1 Day 1 swab sample collected on 06-AUG-2020 is correctly entered in EDC. Per PPD portal, swab sample dated 14-AUG-2020 is reported under Illness Visit Day 1 in PPD portal however, swab sample of 14-AUG-2020 is missing in EDC. Kindly review if the swab sample for 14-AUG-2020 was collected, if yes, consider updating date of test as appropriate, also clarify in site response, if 06-AUG-2020 swab sample was collected for visit 1 day 1 or specify the correct visit name.' answered with 'Specimen producing positive covid was done on Subject V1 conducted on 06AUG2020. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	29 Jan 2021 17:56:00
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "V1D1 requires a covid 19 test."; however, visit 1 Day 1 swab sample collected on 06-AUG-2020 is correctly entered in EDC. Per PPD portal, swab sample dated 14-AUG-2020 is reported under Illness Visit Day 1 in PPD portal however, swab sample of 14-AUG-2020 is missing in EDC. Kindly review if the swab sample for 14-AUG-2020 was collected, if yes, consider updating date of test as appropriate, also clarify in site response, if 06-AUG-2020 swab sample was collected for visit 1 day 1 or specify the correct visit name.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:18:05

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Date of Test

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab Sample Collection Date is reported as 06AUG2020 under Covid-19 Assessment visit in EDC. However same is reported as Visit 1 Day 1 in PPD Central lab. Please confirm the sample collection date and provide both Accession number and the tracking details in the response. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:18:05
Query 'Per GCL Lab Reconciliation: Swab Sample Collection Date is reported as 06AUG2020 under Covid-19 Assessment visit in EDC. However same is reported as Visit 1 Day 1 in PPD Central lab. Please confirm the sample collection date and provide both Accession number and the tracking details in the response. Else clarify, thank you.' answered with 'V1D1 requires a covid 19 test. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	28 Jan 2021 15:13:53
User opened query 'Per GCL Lab Reconciliation: Swab Sample Collection Date is reported as 06AUG2020 under Covid-19 Assessment visit in EDC. However same is reported as Visit 1 Day 1 in PPD Central lab. Please confirm the sample collection date and provide both Accession number and the tracking details in the response. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 05:08:04
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:10
User entered '6 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:07:04
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
Un-reviewed for Data Management.	(b) (4), (b) (6)	29 Jan 2021 05:18:09
Reviewed for Data Management.	(b) (4), (b) (6)	29 Jan 2021 05:18:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:07:04
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:28
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:34
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	30 Sep 2020 17:33:43
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	29 Sep 2020 20:07:06
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 20:07:06
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:40:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	24 Sep 2020 16:40:52
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:40:33
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	24 Sep 2020 16:40:33
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:36
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 20:07:38
User entered 'n/a' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 20:07:29
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 20:07:06
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:40:52
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:44:38
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:33:43
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:24:01

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Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:07:04

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:39
Amendment Manager: User entered '1'	System	21 Aug 2020 02:34:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:21
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:23
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:26
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
User entered '15'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:47:27
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:33
User entered empty.	Afifah Ayub (b) (4)	13 Oct 2020 17:50:12
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:36
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:47:37
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:51:03
User entered '84'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? is 'NO', however there is data present for 'Oxygen saturation'? Please review/update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:52:45
Query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? is 'NO', however there is data present for 'Oxygen saturation'? Please review/update accordingly.' answered with 'Updated' (Site from DM).	Heather Leary (b) (4) (b) (4)	21 Jan 2021 18:19:26
User opened query 'Per CDM: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? is 'NO', however there is data present for 'Oxygen saturation'? Please review/update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 18:18:06
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:21:30
User closed query 'Per source O2 saturation was not collected. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 02:21:26
Query 'Per source O2 saturation was not collected. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:04:41
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:04:26
User opened query 'Per source O2 saturation was not collected. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:51:34
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:34:08
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	21 Jan 2021 18:19:19
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	21 Jan 2021 18:19:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:53
User entered missing code ND - Not Done.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:43
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:26:32
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:17
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:51:45
User entered empty.	Afifah Ayub (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	(b) (4) System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:50:12
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04

PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:49
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4) (b) (4)	13 Oct 2020 17:51:03
User entered missing code ND - Not Done.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:26:32
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:17
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

FDA-CBER-2022-1614-0618270

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:53
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:26:32
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:17
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:09
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:14
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:16
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:17
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:22
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:24
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:26
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:29
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:30
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:52:32
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

FDA-CBER-2022-1614-0618283

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:34
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:35
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:26:17

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:19:14
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:52:58
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:17
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	Likhitha Pabba (4134 - likhitha142)	05 Jan 2021 07:21:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:37
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:39
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:44
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:46
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:47
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:52:49
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:19:18
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Heather Leary (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:50
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:52
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:34:16
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Heather Leary (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	20 Jan 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:53
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:55
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:19:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	20 Jan 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:57
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:52:59
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:34:19
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	(b) (4) Heather Leary (b) (4)	20 Jan 2021 21:02:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4)	20 Jan 2021 21:02:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:01
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:02
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:04
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

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US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:05
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:26:17

US3212066

Folder: Covid-19 Assessment 14 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:07:04

Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:09
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:26:32
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:26:17
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:10
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:07:04
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:43
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:12
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:26:17

US3212066
Folder: Covid-19 Assessment 14 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:07:04
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:48:51
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:05:24
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 17:12:22
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:13:24

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:58:34
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:58:35
User entered '16 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:59:34
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:59:35
User entered '18 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:05
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:06
User entered '20 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:07:04
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:34
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:35
User entered '22 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:48
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:54
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:56:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:56:02
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:55:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:00:55
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:07:04
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:47:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:56:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:56:02
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:56:02
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:55:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

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US3212066

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:47:00
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 16:55:57

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066
Folder: Illness Visit (5)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:07:04
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 06JAN2021 is reported in PPD central lab with 06JAN2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:49:07
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 06JAN2021 is reported in PPD central lab with 06JAN2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'please see ppd lab portal sample received and processes ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	20 Jan 2021 02:08:21
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 06JAN2021 is reported in PPD central lab with 06JAN2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 07:55:37
User entered '06 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066
Folder: Illness Visit (5)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:07:04
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:07:04

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:07:04

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:35:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit (5)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:56

US3212066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:56
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:27:25

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:56
User entered '14 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:27:25

US3212066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:51:56
User entered 'Clinic (Clinic)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:27:25

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'SICKD1'	System	18 Aug 2020 19:27:25

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '14 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '21:13'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered '14 Aug 2020 21:13'	System	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '63' in	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17
DataPoint set to visible.	System	18 Aug 2020 19:27:25

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '148' lb	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17
DataPoint set to visible.	System	18 Aug 2020 19:27:25

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '97.5' F	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered 'Oral (Oral)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '84'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'bpm'	System	18 Aug 2020 19:28:17

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '15'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'breaths/min'	System	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '101'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'mmHg'	System	18 Aug 2020 19:28:17

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:10
User entered '78'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'mmHg'	System	18 Aug 2020 19:28:17

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US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31

Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:31
User entered 'No (N)'	Heather Leary (b) (4)	18 Aug 2020 19:28:42

US3212066
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:31
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:42

US3212066

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:56:52
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:28:54

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:56:52
User entered '14 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 19:28:54
	(b) (4)	

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US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Height *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Height *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Height *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight *(xxx.x)*

Audit	User	Time (GMT)
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:04:26

US3212066

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'SICKD1'	System	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '12:20'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered '04 Jan 2021 12:20'	System	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10
DataPoint set to visible.	System	07 Jan 2021 18:04:26

Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered missing code ND - Not Done.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10
DataPoint set to visible.	System	07 Jan 2021 18:04:26

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

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US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '89'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'bpm'	System	07 Jan 2021 18:05:10

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '17'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'breaths/min'	System	07 Jan 2021 18:05:10

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '114'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'mmHg'	System	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '74'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User entered 'mmHg'	System	07 Jan 2021 18:05:10

US3212066
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31

US3212066

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31

US3212066

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:19

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US3212066

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:27

Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:07:04
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:12:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	07 Jan 2021 18:05:27

FDA-CBER-2022-1614-0618407

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:25

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:25

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:25

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD28'	System	29 Sep 2020 17:04:25

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

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US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

Pulse units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:04:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

FDA-CBER-2022-1614-0618421

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:04:33

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:33

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:04:33

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:22
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:40

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:40

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:30
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:15

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:57:30
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:15

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:39

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:39

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:39

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD28'	System	08 Jan 2021 15:34:39

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:34:45

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:34:45

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:34:45

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:45

US3212066
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 15:34:45

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:51

FDA-CBER-2022-1614-0618450

US3212066

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:51

US3212066

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:56

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Jan 2021 15:34:56

FDA-CBER-2022-1614-0618453

US3212066

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

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:20

US3212066

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

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:20

US3212066

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

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinic (Clinic)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:43:20

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
User entered '0'	Heather Leary (b) (4) (b) (4)	22 Apr 2021 14:37:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:08:40

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:38:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 14:37:32
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4) (b) (4)	22 Apr 2021 14:37:14
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:58:01
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:08:40

FDA-CBER-2022-1614-0618461

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Placebo (Placebo)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Placebo (Placebo)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:07:04
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Placebo (Placebo)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	28 Jan 2021 20:43:45

US3212066

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

Form: Unblinding

Generated On: 11 Aug 2021 22:07:04

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	28 Jan 2021 20:43:45

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:07:04
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered empty.	System	28 Jan 2021 20:45:26
DataPoint set to visible.	System	28 Jan 2021 20:43:45

US3212066

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered empty.	System	28 Jan 2021 20:45:26
DataPoint set to visible.	System	28 Jan 2021 20:43:45

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	07 Apr 2021 20:39:46
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	05 Apr 2021 18:44:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '10:52'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '28 Jan 2021 10:52'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '97.2' F	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '78'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'bpm'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '16'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'breaths/min'	System	28 Jan 2021 20:45:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '107'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

FDA-CBER-2022-1614-0618487

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '77'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

FDA-CBER-2022-1614-0618492

US3212066

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:07:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered empty.	System	28 Jan 2021 20:45:26
DataPoint set to visible.	System	28 Jan 2021 20:43:45

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '12:11'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '28 Jan 2021 12:11'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.1' F	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '71'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'bpm'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '17'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'breaths/min'	System	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '110'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

US3212066

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	28 Jan 2021 20:45:26

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '76'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	28 Jan 2021 20:45:26

Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:07:04
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:36

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:45:36

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:48:12
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:43

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:48:11
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:43

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:48:10
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:43

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mRNA-1273'	System	28 Jan 2021 20:46:43
DataPoint set to visible.	System	28 Jan 2021 20:43:45

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:48:07
User entered '28 Jan 2021'	Heather Leary (b) (4)	28 Jan 2021 20:46:43

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	08 Apr 2021 18:44:34
DataPoint Un-verified.	(b) (4) Jagruti Patel (b) (4) (b) (4)	07 Apr 2021 20:39:46
User entered '11:35' reason for change: Data Entry Error	Jagruti Patel (b) (4) (b) (4)	07 Apr 2021 20:39:46
User closed query 'Per source dose was administered at 10:35. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:21:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:21:16
Signature has been broken.	Jagruti Patel (b) (4) (b) (4)	05 Apr 2021 18:44:34
User entered '10:35' reason for change: Data Entry Error	Jagruti Patel (b) (4) (b) (4)	05 Apr 2021 18:44:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
Query 'Per source dose was administered at 10:35. Please verify and update accordingly. ' answered with 'verified source: study vaccine administered in Left arm on 28JAN2021 @ 11:35 for OL-D1 ' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	02 Apr 2021 16:46:56
User opened query 'Per source dose was administered at 10:35. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:47:58
User entered '11:35'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:43

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '28 Jan 2021 11:35'	System	07 Apr 2021 20:39:46
User entered '28 Jan 2021 10:35'	System	05 Apr 2021 18:44:34
User entered '28 Jan 2021 11:35'	System	28 Jan 2021 20:46:43

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:48:03
User entered 'Left Arm (LEFT ARM)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:43

US3212066

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

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:48:05
User entered 'ONCE'	System	28 Jan 2021 20:46:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 20:46:43

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Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:55

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '11:10'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:46:55

FDA-CBER-2022-1614-0618524

US3212066

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '28 Jan 2021 11:10'	System	28 Jan 2021 20:46:55

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:07:04

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:47:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Jan 2021'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:47:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '11:05'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:47:06

US3212066

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:07:04

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '28 Jan 2021 11:05'	System	28 Jan 2021 20:47:06

US3212066

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

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Jan 2021 20:47:10

US3212066

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

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	28 Jan 2021 20:47:10

US3212066
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 15:24:25

US3212066

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '04 Feb 2021'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 15:24:25

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 15:24:25

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US3212066
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Feb 2021 15:24:25

US3212066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 15:24:31

US3212066
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:07:04
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	09 Feb 2021 15:24:31

US3212066

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	09 Feb 2021 15:24:31
DataPoint set to visible.	System	09 Feb 2021 15:24:31

US3212066
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:30:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:30:19

US3212066

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:30:19

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'OLD29'	System	01 Mar 2021 15:30:19

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '12:41'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '26 Feb 2021 12:41'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.0' F	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '79'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'bpm'	System	01 Mar 2021 15:34:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '16'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'breaths/min'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '97'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '74'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered '26 Feb 2021'	Laura Ngansop Djampou	01 Mar 2021 15:34:46
	(b) (4)	

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered '14:21'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '26 Feb 2021 14:21'	System	01 Mar 2021 15:34:46

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US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '98.1' F	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '76'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'bpm'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '16'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'breaths/min'	System	01 Mar 2021 15:34:46

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '102'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

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US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	01 Mar 2021 15:34:46

US3212066

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '74'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:34:46

US3212066
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mmHg'	System	01 Mar 2021 15:34:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:49

FDA-CBER-2022-1614-0618575

US3212066

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:37:49

US3212066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'mRNA-1273'	System	01 Mar 2021 15:38:09
DataPoint set to visible.	System	09 Feb 2021 15:24:31

US3212066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:07:04

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '13:42'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '26 Feb 2021 13:42'	System	01 Mar 2021 15:38:09

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:09

US3212066
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'ONCE'	System	01 Mar 2021 15:38:09

US3212066
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:07:04
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 15:38:09

US3212066

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 15:38:14

US3212066

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	01 Mar 2021 15:38:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:11:53

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '05 Mar 2021'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:11:53

US3212066

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:07:04

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:11:53

US3212066
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:07:04
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:11:53

US3212066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered 'Yes (Y)'	Laura Ngansop Djampou	08 Mar 2021 19:12:01
	(b) (4)	

US3212066

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:07:04

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:45
User entered '1'	System	08 Mar 2021 19:12:01

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 13:44:46

US3212066
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 13:44:46

US3212066

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Apr 2021 13:44:46

US3212066
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:07:04
Folder OID

Audit	User	Time (GMT)
User entered 'OLD57'	System	02 Apr 2021 13:44:46

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '01 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered '10:08'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '01 Apr 2021 10:08'	System	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '97.9' F	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '81'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '17'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 13:45:41

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '114'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:07:04

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered '88'	(b) (4), (b) (6)	02 Apr 2021 13:45:41

US3212066
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:07:04
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 13:45:41

US3212066

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 13:46:29

US3212066

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:07:04

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 13:46:29

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 13:57:21

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 13:57:21

FDA-CBER-2022-1614-0618617

US3212066

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 13:57:21

US3212066

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:07:04

Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 13:57:21

US3212066
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:07:04
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:36:09
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:55:17
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'added' (Site from DM).	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:41:17
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 08:02:39
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" in Adverse event summary page, however adverse events recorded in corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:32:51

US3212066
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:07:04

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" in Adverse event summary page, however adverse events recorded in corresponding page. Please review and update accordingly. else clarify' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4) (b) (4)	13 Jan 2021 17:28:51
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4) (b) (4)	13 Jan 2021 17:28:46
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" in Adverse event summary page, however adverse events recorded in corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 14:54:53
User closed query 'Per CDM: it appears event was removed. Please consider recording this as No' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:59:47
Query 'Per CDM: it appears event was removed. Please consider recording this as No' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:35:48
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:35:45
User entered 'No (N)' reason for change: New Information	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 15:35:45
User opened query 'Per CDM: it appears event was removed. Please consider recording this as No' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:49
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:38:23
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 20:02:40

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

AEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:28:53
User entered 'USA-US115-2020-mRNA-1273-P301000002'	System	24 Aug 2020 19:28:32
User entered 'New'	(b) (4), (b) (6)	24 Aug 2020 19:28:32

US3212066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:07:04
Adverse event

Audit	User	Time (GMT)
User closed query 'Per CDM: per sponsor review, Please confirm Covid-19 positive test at screening. If positive at screening please delete from AE listing as not meeting criteria for being reported in AE listing. If the participant was positive at screening fill form DOSING DISCONTINUATION and mark 'Due to SARS-COV-2' ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 05:08:37
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:20:52
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:13:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:13:50
Data point term sent to Coder	System	22 Apr 2021 13:13:19
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:35
Coding entries removed.	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:35
User entered 'COVID-19' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:35
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 21:04:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 21:04:44
Query 'Per CDM: per sponsor review, Please confirm Covid-19 positive test at screening. If positive at screening please delete from AE listing as not meeting criteria for being reported in AE listing. If the participant was positive at screening fill form DOSING DISCONTINUATION and mark 'Due to SARS-COV-2' ' answered with 'reactivated due to subsequent query' (Site from DM).	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:42
Data point term sent to Coder	System	21 Apr 2021 21:03:17
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
Data point term sent to Coder	System	04 Dec 2020 22:03:21

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Adverse event

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
Data point term sent to Coder	System	16 Nov 2020 23:03:11
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
User opened query 'Per CDM: per sponsor review, Please confirm Covid-19 positive test at screening. If positive at screening please delete from AE listing as not meeting criteria for being reported in AE listing. If the participant was positive at screening fill form DOSING DISCONTINUATION and mark 'Due to SARS-COV-2' ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:05:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:37
Data point term sent to Coder	System	18 Aug 2020 19:43:02
User entered 'COVID19'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:42:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:42:26
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:42:11
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 17:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 17:10:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:28:32
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:28:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

US3212066
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:25:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:21:59
DataPoint Un-verified.	Heather Leary (b) (4)	22 Apr 2021 13:12:35
User entered '09 Aug 2020' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:35
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'PV query: The AE data field for event start date is currently reported as 13-AUG-2020. However, real-time reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal SARS-CoV-2 test specimen obtained on 06-AUG-2020. Please consider change of event start date to 06-AUG-2020 ? ' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:27:24
Query 'PV query: The AE data field for event start date is currently reported as 13-AUG-2020. However, real-time reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal SARS-CoV-2 test specimen obtained on 06-AUG-2020. Please consider change of event start date to 06-AUG-2020 ? ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:45:26
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:39:22
User opened query 'PV query: The AE data field for event start date is currently reported as 13-AUG-2020. However, real-time reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal SARS-CoV-2 test specimen obtained on 06-AUG-2020. Please consider change of event start date to 06-AUG-2020 ? ' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:26:30

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3212066

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medical safety query: The AE data field for event start date is currently reported as 13-AUG-2020. However, real-time reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal SARS-CoV-2 test specimen obtained on 06-AUG-2020. Please consider change of event start date to 06-AUG-2020 ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 15:26:16
User opened query 'Medical safety query: The AE data field for event start date is currently reported as 13-AUG-2020. However, real-time reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal SARS-CoV-2 test specimen obtained on 06-AUG-2020. Please consider change of event start date to 06-AUG-2020 ' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 20:55:44
User entered '13 Aug 2020' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:55:50
User entered '6 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:22:13
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Apr 2021 13:12:46
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:46
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:46
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Apr 2021 13:12:35
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '11:40' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:39:22
User closed query 'PV Query: Please clarify the start time of 14:30. Was this the time the results returned from the lab?' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 20:24:39
Query 'PV Query: Please clarify the start time of 14:30. Was this the time the results returned from the lab?' answered with 'RESULTS RECEIVED ON 13AUG, CONVALESCENT VISITS BEGAN ON 14AUG20' (Site from Safety).	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:56:28
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 20:56:21
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:56:21
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 20:55:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify the start time of 14:30. Was this the time the results returned from the lab?' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:54:25
User entered '14:30'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 13:12:46
User entered '09 Aug 2020 11:40'	System	22 Apr 2021 13:12:35
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
User entered '06 Aug 2020 11:40'	System	25 Sep 2020 17:39:22
User entered empty.	System	31 Aug 2020 20:56:21
User entered '13 Aug 2020 14:30'	System	31 Aug 2020 20:55:50
User entered '6 Aug 2020 14:30'	System	18 Aug 2020 19:42:11

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Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'PV Query: Please clarify event end date as patient was still experiencing signs/symptoms of COVID-19 on 25 Aug 2020. Please consider updating event end date to resolution of symptoms, or update outcome to resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:27:26
Query 'PV Query: Please clarify event end date as patient was still experiencing signs/symptoms of COVID-19 on 25 Aug 2020. Please consider updating event end date to resolution of symptoms, or update outcome to resolved with sequelae.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:45:35
User opened query 'PV Query: Please clarify event end date as patient was still experiencing signs/symptoms of COVID-19 on 25 Aug 2020. Please consider updating event end date to resolution of symptoms, or update outcome to resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:58:26
Query 'PV Query: Please clarify event end date as patient was still experiencing signs/symptoms of COVID-19. Please consider updating event end date to resolution of symptoms.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:58:11
User opened query 'PV Query: Please clarify event end date as patient was still experiencing signs/symptoms of COVID-19. Please consider updating event end date to resolution of symptoms.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:22:33
User entered '25 Aug 2020' reason for change: New Information	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Form: Adverse Events (1)
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End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Apr 2021 13:12:35
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 11:04:55
User closed query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time (06 AUG 2020, 12:23 hrs)? Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:04:53
Query 'Data is required. Please provide.' answered with 'End time is not within 24 hours of dosing time' (Site from System).	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 15:31:18
Query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time (06 AUG 2020, 12:23 hrs)? Please review and amend accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 15:31:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Oct 2020 15:30:59
User entered empty; reason for change New Information	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 15:30:59
User opened query 'Per CDM: Please note this field is not required, unless End time is within 24 hours of dosing time (06 AUG 2020, 12:23 hrs)? Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 22:32:32
User entered '21:00' reason for change: New Information	(b) (4), (b) (6)	25 Sep 2020 17:39:22
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	31 Aug 2020 20:56:36

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End time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:56:36
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	31 Aug 2020 20:55:50
User entered '21:00' reason for change: New Information	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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AE End Date and Time (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
User entered empty.	System	09 Oct 2020 15:30:59
User entered '25 Aug 2020 21:00'	System	25 Sep 2020 17:39:22
User entered empty.	System	31 Aug 2020 20:56:36
User entered '25 Aug 2020 21:00'	System	27 Aug 2020 17:10:11
User entered empty.	System	18 Aug 2020 19:42:11

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Severity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Form: Adverse Events (1)

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Form: Adverse Events (1)

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Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'PV Query: As subject was given study drug, please update causality to study drug from not applicable to not related or related.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:51:03
Query 'PV Query: As subject was given study drug, please update causality to study drug from not applicable to not related or related.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4) (b) (4)	02 Oct 2020 21:34:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	02 Oct 2020 21:34:11
User opened query 'PV Query: As subject was given study drug, please update causality to study drug from not applicable to not related or related.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:00:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:14:28
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	25 Sep 2020 17:47:57
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	25 Sep 2020 17:47:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:47:57

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Relationship to investigational product

Audit	User	Time (GMT)
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	25 Sep 2020 17:39:22
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:41:56
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:24
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 17:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 17:10:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 20:33:31
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:42:11
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 17:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 17:10:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:42:11
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 05:08:47
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
User closed query 'Per source, 2nd dose was not given. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:29:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:29:38
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated per prior query' (Site from System).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:13:09
Query 'Per source, 2nd dose was not given. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:57
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Apr 2021 13:12:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	22 Apr 2021 13:12:35
User opened query 'Per source, 2nd dose was not given. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:26:56
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Apr 2021 21:05:01
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	21 Apr 2021 21:05:01

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:05:01
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:05:01
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Apr 2021 21:03:01
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Dec 2020 22:03:02
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	04 Dec 2020 22:03:02
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Dec 2020 22:02:27
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
User closed query 'Per DM CLR - RQ: Site's response noted. However, please note that Date of Dosing discontinuation is 11SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:42:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, please note that Date of Dosing discontinuation is 11SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify.\ ' answered with 'Subject was positive at baseline. AE resolved before subject came back for visit 2 at which point treatment was discontinued' (Site from DM).	Anna Pena (b) (4) (b) (4)	06 Nov 2020 15:50:00
User opened query 'Per DM CLR - RQ: Site's response noted. However, please note that Date of Dosing discontinuation is 11SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:06:51
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:06:51
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:07:34
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:12:19
User closed query 'PV Query: Please consider updating action taken as patient had received study drug. If patient is not to continue in study, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:27:30

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating action taken as patient had received study drug. If patient is not to continue in study, please consider updating action taken to withdrawn.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:46:41
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:39:22
User opened query 'PV Query: Please consider updating action taken as patient had received study drug. If patient is not to continue in study, please consider updating action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:21:06
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 17:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 17:10:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:42:11
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

None

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '1'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered '0'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Leary (b) (4) (b) (4)	27 Aug 2020 17:10:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:25:20
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:19
User closed query 'PV Query: The event of COVID19 was diagnosed on 13 Aug2020, but not reported until 24Aug2020. Please clarify the reason for the delay in reporting the event of COVID19.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:27:36
User closed query 'PV Query: Please confirm if a second SARS-CoV-2 test was performed on 22 Aug 2020. If so, please provide the indication for additional testing.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 14:27:34
Query 'PV Query: The event of COVID19 was diagnosed on 13 Aug2020, but not reported until 24Aug2020. Please clarify the reason for the delay in reporting the event of COVID19.' answered with 'Subject was notified in a timely manner - safety email was sent later - inadvertently missed' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:47:45
Query 'PV Query: Please confirm if a second SARS-CoV-2 test was performed on 22 Aug 2020. If so, please provide the indication for additional testing.' answered with 'Second NP test was not done' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:46:57
User opened query 'PV Query: The event of COVID19 was diagnosed on 13 Aug2020, but not reported until 24Aug2020. Please clarify the reason for the delay in reporting the event of COVID19.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:59:19

Folder: Adverse Events

Form: Adverse Events (1)

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: The event of COVID19 was diagnosed on 06Aug2020, but not reported until 24Aug2020. Please clarify the reason for the delay in reporting the event of COVID19.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:59:14
User closed query 'PV Query: Please report if the patient had any known exposures or other risk factors that would put them at risk for COVID infection.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 20:24:24
User opened query 'PV Query: Please confirm if a second SARS-CoV-2 test was performed on 22 Aug 2020. If so, please provide the indication for additional testing.' (Site from Safety).	(b) (4), (b) (6)	01 Sep 2020 14:22:50
Query 'PV Query: Please report if the patient had any known exposures or other risk factors that would put them at risk for COVID infection.' answered with 'Subject is hospital employee and cohabitates with someone working at high occupational risk job' (Site from Safety).	Heather Leary (b) (4) (b) (4)	31 Aug 2020 21:08:04
User entered 'SUBJECT TESTED POSITIVE FOR COVID19 AT BASELINE/SCREENING VISIT; LAB RESULTS RECEIVED 13AUG2020. ILLNESS VISIT AND CONVALESCENT VISITS BEGAN 14AUG2020. SUBJECT IS A HOSPITAL WORKER AND COHABITATES WITH SOMEONE WORKING A HIGH OCCUPATIONAL RISK JOB. SUBJECT REPORTS fatigue, intermittent sinus headache sometimes reaching 6/10 on pain scale, complete loss of taste and smell, and nausea. ALL SYMPTOMS RESOLVED BY 25AUG2020' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	31 Aug 2020 21:05:09
User opened query 'PV Query: Please report if the patient had any known exposures or other risk factors that would put them at risk for COVID infection.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:54:08
User opened query 'PV Query: The event of COVID19 was diagnosed on 06Aug2020, but not reported until 24Aug2020. Please clarify the reason for the delay in reporting the event of COVID19.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 18:53:57

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:07:04
Narrative

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:42:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
Amendment Manager: User entered '0'	System	21 Aug 2020 02:34:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
Amendment Manager: User entered '1'	System	21 Aug 2020 02:34:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:03:01
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:02:27
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	16 Nov 2020 23:02:58
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:34:06

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:35
User closed query 'Please reactivate Log Line #1. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:23:03
Query 'Please reactivate Log Line #1. Please verify and update accordingly.' answered with 'reactivated' (Site from CRA).	Heather Leary (b) (4) (b) (4)	21 Apr 2021 21:05:38
User opened query 'Please reactivate Log Line #1. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:57:48
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 01:28:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 01:28:57
Data point term sent to Coder	System	11 Jan 2021 01:28:23
User entered 'Acute sinusitis'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:08
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:30
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:48
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:29
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '28 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:52
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
User entered empty.	System	11 Jan 2021 01:28:04

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Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:27
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '02 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

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AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
User entered empty.	System	11 Jan 2021 01:28:04

US3212066

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:00
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:55
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:13
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:39:48
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:45:27
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:45:47
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:00
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:12
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:28
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:40
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:58
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:47:16
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:47:30
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

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Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:33:04
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:47:51
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'None (NONE)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:05
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:17
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '1'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:28
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:07:04

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:47
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:29
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

US3212066
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:07:04
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:54
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
User entered '0'	System	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15
User entered '1'	System	11 Jan 2021 01:28:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:56
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 18:57:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:33:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:33:38
Data point term sent to Coder	System	09 Apr 2021 14:46:58
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' (Site from System).	System	09 Apr 2021 14:46:25
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' answered with 'updated' (Site from System).	Heather Leary (b) (4) (b) (4)	09 Apr 2021 14:46:25
Signature has been broken.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 14:46:09
User entered 'HUMAN ENTEROVIRUS/RHINOVIRUS' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	09 Apr 2021 14:46:09
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:15:31
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
Data point term sent to Coder	System	08 Mar 2021 19:13:46
User entered 'upper respiratory infection due to human enterovirus/rhinovirus'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

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Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:52:08
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:52:28
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:52:45
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:53:11
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '24 Dec 2020'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

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Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:54:48
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
User entered empty.	System	08 Mar 2021 19:13:18

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:07:04
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:55:20
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:57:03
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '02 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:07:04
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:57:16
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
User entered empty.	System	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:57:34
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:57:46
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:58:07
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:58:21
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:58:34
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:59:19
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:03:10
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:03:42
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:07:04
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:04:11
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:04:24
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:04:38
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:04:54
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:09
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:33:17
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:24
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'None (NONE)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:07:04
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:37
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '1'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 11 Aug 2021 22:07:04
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:05:52
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:07
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:24
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:45
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:06:59
User signature succeeded.	Vicki Miller (b) (4) (b) (4) (b) (4)	31 Mar 2021 00:55:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Mar 2021 19:13:18

US3212066

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
User entered '0'	System	08 Mar 2021 19:13:18

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16
User entered '1'	System	08 Mar 2021 19:13:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:16

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:10:01
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:41:38
Data point term sent to Coder	System	19 Apr 2021 13:40:59
User entered 'fatigue'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:10:14
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:10:30
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:10:43
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:11:06
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '07 Aug 2020'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:11:19
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:56:22
User entered '12:12' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:56:22
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 13:40:59
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
User entered '07 Aug 2020 12:12'	System	19 Apr 2021 15:56:22
User entered empty.	System	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:11:31
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:11:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '16 Aug 2020'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:12:02
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:56:22
User entered '13:32' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:56:22
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 13:40:59
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
User entered '16 Aug 2020 13:32'	System	19 Apr 2021 15:56:22
User entered empty.	System	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:13:13
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:52:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:52:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 18:52:40
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 13:40:59
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:17:41
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

FDA-CBER-2022-1614-0618754

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:19:16
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:19:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:20:16
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:09
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:25
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:21:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:16
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:30
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:22:45
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:04
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:52:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:52:40
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 18:52:40
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 13:40:59
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:52:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:52:40
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 18:52:40
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 13:40:59
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'None (NONE)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '1'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered '0'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

US3212066
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 11 Aug 2021 22:07:04
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:23:34
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	20 Apr 2021 18:37:31
User entered empty.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:40:59

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
User entered '0'	System	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18
User entered '0'	System	19 Apr 2021 13:40:59

US3212066

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:07:04

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:32:18

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:36:09
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:55:40
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:43:59

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:46:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 16:46:18
Data point term sent to Coder	System	06 Aug 2020 16:45:36
User entered 'LISINOPRIL'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:53
User entered 'HYPERTENSION'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:52
User entered '5'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:50
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:47
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:45
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:43
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:41
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:52:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 19:20:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 17:24:12
User entered 'UN UNK 2015'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:40
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:36
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:56:35
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 16:44:36

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:56:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:56:24
Data point term sent to Coder	System	06 Aug 2020 16:45:37
User entered 'Propanalol'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:47
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:50
User entered 'Headaches'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:54
User entered '5'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:55
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:57
User entered 'as needed (PRN)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:00
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:03
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:52:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 19:20:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 17:24:12
User entered 'UN UNK 2018'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:04
User entered '0'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:06
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:07
User entered empty.	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:09
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 16:45:13

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 16:45:13

FDA-CBER-2022-1614-0618812

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 16:45:13

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:54:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:54:16
Data point term sent to Coder	System	11 Aug 2020 13:53:26
User entered 'Acetaminophen'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:22
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:23
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:25:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'solicited adverse reaction of HEADACHES did not meet the AE reporting criteria.' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:01:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria.\<br /\>' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:48:00
User entered 'Headaches'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:27
User entered '500'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:29
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:30
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:32
User entered 'as needed (PRN)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:33
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:35
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:37
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:17:00
User entered '09 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:17:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:39
User entered '9 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

FDA-CBER-2022-1614-0618825

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:42
User entered '0'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:43
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:44
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:46
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:53:03

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:53:03

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:52
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 09:24:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 09:24:32
Data point term sent to Coder	System	21 Sep 2020 16:03:06
Coding entries removed.	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:02:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:01:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:01:17
Data point term sent to Coder	System	12 Aug 2020 15:01:17
User entered 'Prednisone'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:53
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:15:13
Query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'per CDM : If positive at screening please delete from AE listing as not meeting criteria for being reported in AE listing. If the participant was positive at screening fill form DOSING DISCONTINUATION and mark 'Due to SARS-COV-2'' (Site from DM).	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 22:03:39
User opened query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:08:29
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:02:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:23:09

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:02:43
User entered 'COVID-19' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:02:22
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:48:26
User entered 'Headaches'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:03:01
User entered '50'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:03:02
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:03:04
User entered empty.	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per source, frequency of is once daily (QD). Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:59:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:59:03
Query 'Per source, frequency of is once daily (QD). Please verify and update accordingly. ' answered with 'Verified and updated' (Site from CRA).	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:29:20
User entered 'once daily (QD)' reason for change: Per Query Resolution	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:29:05
User opened query 'Per source, frequency of is once daily (QD). Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:03:55
User entered 'as needed (PRN)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:03:57
User entered empty.	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:00
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:01
User entered empty.	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:04:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 10AUG2020.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:23:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 10AUG2020.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	23 Sep 2020 21:13:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 10AUG2020.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:47:05
User entered '10 Aug 2020'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:06
User entered '0'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:08
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:02:22
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:11
User entered '15 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	23 Sep 2020 21:13:46
User entered '25 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 16:02:22
User entered empty.	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:04:13
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:06:17
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	16 Oct 2020 17:52:35
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	16 Oct 2020 17:51:55
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:02:17
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User entered '1'	System	02 Nov 2020 22:29:05
User entered empty.	System	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User entered '1'	System	02 Nov 2020 22:29:05
User entered empty.	System	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:32
User entered '804 (804)'	System	02 Nov 2020 22:29:05
User entered empty.	System	12 Aug 2020 15:01:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per DM CLR: Please review if medications IMITREX, TOPIRAMATE and TYLENOL were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:55:17
Query 'Per DM CLR: Please review if medications IMITREX, TOPIRAMATE and TYLENOL were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' answered with 'Subject did not have a change in medications due to the worsening of her headaches but to provide better control of them. ' (Site from DM).	Nirja Shah (b) (4) (b) (4)	06 Nov 2020 14:36:13
User opened query 'Per DM CLR: Please review if medications IMITREX, TOPIRAMATE and TYLENOL were added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:42:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:18:39
Data point term sent to Coder	System	04 Sep 2020 15:17:50
User entered 'Tylenol'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:24
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:01:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with ' the solicited adverse reaction did not meet the AE reporting criteria.' (Site from DM).	Heather Leary (b) (4) (b) (4)	16 Oct 2020 15:50:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:02:30
User entered 'Headache'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:30
User entered '650'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:32
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:33
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:36
User entered 'as needed (PRN)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:40
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:44
User entered '09 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:46
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:47
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:04:50
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 15:17:23

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:48:43
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHES should be recorded, and update con med indication or provide clarification. ' answered with 'After visiting her doctor, she was switched from Imitrex to Topiramate for her migraine headaches. ' (Site from DM).	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:37:42
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 02:30:14
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:34:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:34:21
Data point term sent to Coder	System	09 Oct 2020 16:33:15
User entered 'Topiramate'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:02
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:03
User entered 'migraine headaches'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:07
User entered '50'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:08
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:13
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:18
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:20
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:22
User entered '29 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:23
User entered '0'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:27
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:05:30
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:32:35

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 16:32:35

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:28:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:28:02
Data point term sent to Coder	System	02 Nov 2020 22:39:22
Coding entries removed.	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:39:08
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:34:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:34:20
Data point term sent to Coder	System	09 Oct 2020 16:33:16
User entered 'Imitrex'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:12
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:59:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:57:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'medication was changed for better control of medical history item "migraine headaches" Not solicited event or AE ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	03 Nov 2020 19:00:23
DataPoint Un-verified.	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:39:08
User entered 'Migraine Headaches' reason for change: Per Query Resolution	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:39:08

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 02:29:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:14
User entered 'Headache'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per source, dose is 50. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:59:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:59:27
Query 'Per source, dose is 50. Please verify and update accordingly.' answered with 'verified and updated' (Site from CRA).	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:39:29
User entered '50' reason for change: Data Entry Error	Nirja Shah (b) (4) (b) (4)	02 Nov 2020 22:39:08
User opened query 'Per source, dose is 50. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:06:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:26
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:15
User entered 'unk'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:59
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:01
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:03
User entered 'as needed (PRN)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:04
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:07
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:08
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:10
User entered '07 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:12
User entered '0'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:13
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:55:38
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'Not a solicited event, linked to medical history. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	04 Nov 2020 15:18:27
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 02:30:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:17
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	09 Oct 2020 16:33:04

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US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:33:04

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 16:20:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 16:20:09
Data point term sent to Coder	System	04 Dec 2020 16:18:57
User entered 'Influenza Vaccine'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Immunization'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0.5'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'mL (mL)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User entered '06 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '06 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User entered empty.	System	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User entered empty.	System	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:39
User entered empty.	System	04 Dec 2020 16:18:33

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 16:39:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:39:02
Data point term sent to Coder	System	11 Jan 2021 01:29:23
User entered 'Prednisone'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'acute sinusitis'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '20'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'three times daily (TID)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 11 Aug 2021 22:07:04
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

FDA-CBER-2022-1614-0618933

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

FDA-CBER-2022-1614-0618937

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '29 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:29:21

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User entered '3'	System	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User entered '1'	System	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:44
User entered '804 (804)'	System	11 Jan 2021 01:29:21

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 16:54:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:54:02
Data point term sent to Coder	System	11 Jan 2021 01:31:24
User entered 'prednisone'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

FDA-CBER-2022-1614-0618945

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'acute sinusitis'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '20'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

FDA-CBER-2022-1614-0618947

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'twice daily (BID)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '30 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '02 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User entered '2'	System	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User entered '1'	System	11 Jan 2021 01:30:28

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:36:52
User entered '804 (804)'	System	11 Jan 2021 01:30:28

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 17:21:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 17:21:43
Data point term sent to Coder	System	11 Jan 2021 01:31:25
User entered 'Zithromax'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'acute sinusitis'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '500'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '28 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered '02 Jan 2021'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	11 Jan 2021 01:31:16

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User entered '1'	System	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:07:04

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User entered '1'	System	11 Jan 2021 01:31:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:37:03
User entered '804 (804)'	System	11 Jan 2021 01:31:16

US3212066

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:07:04

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:07:35
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	06 Aug 2020 16:45:26

US3212066

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:07:04

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:24:41
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Please verify date as this is past the date of expected dose 2 date - should be before or on the expected date.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:23:25
Query 'Please verify date as this is past the date of expected dose 2 date - should be before or on the expected date.' answered with 'Subject tested positive for COVID at her baseline visit on 06AUG2020, we received lab results back onsite on 13AUG2020' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	15 Dec 2020 15:36:43
User entered '13 Aug 2020' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	15 Dec 2020 15:36:16
User opened query 'Please verify date as this is past the date of expected dose 2 date - should be before or on the expected date.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 21:45:21
User entered '11 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:07:09

US3212066
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:07:04
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:24:41
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User closed query 'Per CDM: it appears the event of Void-19 has been removed yet there is a diagnostic test recorded as positive dated 14AUG2020 and reason for dosing discontinuation is recorded as AE of Covid-19. Please review and reconcile making all applicable updates.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:04:50
Query 'Per CDM: it appears the event of Void-19 has been removed yet there is a diagnostic test recorded as positive dated 14AUG2020 and reason for dosing discontinuation is recorded as AE of Covid-19. Please review and reconcile making all applicable updates.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 16:15:07
User entered 'Other (OTHER)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 16:14:56
User opened query 'Per CDM: it appears the event of Void-19 has been removed yet there is a diagnostic test recorded as positive dated 14AUG2020 and reason for dosing discontinuation is recorded as AE of Covid-19. Please review and reconcile making all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:41:56
User entered 'AE (specify) (ADVERSE EVENT)'	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:07:09

US3212066

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:07:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:24:15
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:24:41
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
User entered 'COVID-19 positive results' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	18 Nov 2020 16:13:35
User entered 'COVID Positive results'	Afifah Ayub (b) (4) (b) (4)	05 Nov 2020 21:07:09

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:07:04

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

FDA-CBER-2022-1614-0618991

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:07:04

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

FDA-CBER-2022-1614-0618996

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

FDA-CBER-2022-1614-0619001

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

FDA-CBER-2022-1614-0619004

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 22:07:04
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '24/Aug/2020 15:36'	System	24 Aug 2020 19:36:59

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:07:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered '1'	(b) (4), (b) (6)	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:07:04

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

FDA-CBER-2022-1614-0619020

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 22:07:04
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '27/Aug/2020 14:42'	System	27 Aug 2020 18:42:25

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:07:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 18:42:25

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

FDA-CBER-2022-1614-0619028

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

FDA-CBER-2022-1614-0619034

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '01/Sep/2020 16:25'	System	01 Sep 2020 20:25:40

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:07:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 20:25:40

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

FDA-CBER-2022-1614-0619042

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:07:04

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 11 Aug 2021 22:07:04
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '28/Sep/2020 10:28'	System	28 Sep 2020 14:28:22

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:07:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:51:19
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 14:28:22

Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'USA-US115-2020-MRNA-1273-P301000002'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Aug 2020 19:36:51
User entered 'No (N)'	System	24 Aug 2020 19:28:32

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:45:12

FDA-CBER-2022-1614-0619060

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:27:54
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:45:12

FDA-CBER-2022-1614-0619061

US3212066
Folder: SAE USA-US115-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:07:04
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:03:22
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 18:42:12
User entered 'US' (non-conformant).	System	24 Aug 2020 19:36:59

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:07:04

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	05 Oct 2020 13:51:28
User entered '4'	System	28 Sep 2020 14:28:22
User entered '3'	System	01 Sep 2020 20:25:40
User entered '2'	System	27 Aug 2020 18:42:25
User entered '1'	System	24 Aug 2020 19:36:59

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:07:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '05/Oct/2020 09:51'	System	05 Oct 2020 13:51:28

US3212066

Folder: SAE USA-US115-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:07:04

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:02:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:42
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 13:51:28