

US3212004 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:42:51

All time stamps listed in this document are displayed in GMT

US3212004

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Participant ID

US3212004

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

US3212004

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3212004

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Date of Birth (MMM yyyy)	(b) (6) 1982
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3212004

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Date of Informed Consent (<i>dd MMM yyyy</i>)	03 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3212004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3212004

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Were any significant conditions reported?

Yes ☒

No ☐

US3212004

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3212004

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	CHEILOPLASTY
Start date (dd MMM yyyy)	(b) (6) 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	(b) (6) 1982
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1982
Start Year (derived)	1982
Stop Month and Year (derived)	(b) (6) 1982
Stop Year (derived)	1982

US3212004

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	PALATOPLASTY
Start date (dd MMM yyyy)	(b) (6) 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	(b) (6) 1982
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1982
Start Year (derived)	1982
Stop Month and Year (derived)	(b) (6) 1982
Stop Year (derived)	1982

US3212004

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	02 AUG 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	02 AUG 2004
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2004
Start Year (derived)	2004
Stop Month and Year (derived)	AUG 2004
Stop Year (derived)	2004

US3212004

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3212004

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	CLEFT LIP
Start date (dd MMM yyyy)	(b) (6) 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 1982
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1982
Start Year (derived)	1982
Stop Month and Year (derived)	DEC 1982
Stop Year (derived)	1982

US3212004

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Condition	CLEFT PALATE
Start date (dd MMM yyyy)	(b) (6) 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 1982
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1982
Start Year (derived)	1982
Stop Month and Year (derived)	DEC 1982
Stop Year (derived)	1982

US3212004

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 09:57
Height (xxx.x)	67 in
Weight (xxx.x)	205 lb
BMI (xxx.x)	32.17467 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

US3212004

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

US3212004

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*) 03 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*) 02 AUG 2004

Date of surgery unknown False

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

Date of last menstruation unknown False

US3212004

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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

BUSINESS DEVELOPMENT
MANAGER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3212004

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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 TO THEIR MAIN WORKPLACE MORE THAN 2 DAYS/WEEK; INTERACTS WITH 5 OR MORE PEOPLE DURING THE COURSE OF A TYPICAL WORKDAY; LIVES WITH SCHOOL AGED CHILDREN & WITH SOMEONE IN HIGH RISK JOB

US3212004

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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

Visit date (dd MMM yyyy)	03 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3212004

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 100679

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 ☒

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 09:57
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 12:23
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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.

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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) 03 AUG 2020

What was the treatment time? (00:00-23:59) 11:41 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 11:41

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

US3212004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

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

Collection date (dd MMM yyyy)	03 AUG 2020
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Collection time (00:00-23:59)	11:24 (24 HR)
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Collection date and time (derived)	03 AUG 2020 11:24
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US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	03 AUG 2020 11:20
Nasopharyngeal Swab 2	No		

US3212004

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:22

PC Open Date & Time

03 AUG 2020 12:01

PC Close Date & Time

03 AUG 2020 14:31

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °F

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

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

PC Time Stamp	03 AUG 2020 19:01
PC Open Date & Time	03 AUG 2020 15:26
PC Close Date & Time	04 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

04 AUG 2020 17:04

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 18:13

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 20:45

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:42

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 14:39

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 19:36

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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

03 AUG 2020 12:23

PC Open Date & Time

03 AUG 2020 12:01

PC Close Date & Time

03 AUG 2020 14:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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

03 AUG 2020 19:02

PC Open Date & Time

03 AUG 2020 15:26

PC Close Date & Time

04 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 17:04

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 18:13

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 20:46

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:42

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 14:39

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:34

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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 ☐

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 12:23
PC Open Date & Time	03 AUG 2020 12:01
PC Close Date & Time	03 AUG 2020 14:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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 ☐

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 19:02
PC Open Date & Time	03 AUG 2020 15:26
PC Close Date & Time	04 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

49 of 3188

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 17:05
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 3188

EAB) (1725)

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:14
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3188

EAB) (1725)

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:46
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 3188

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:42
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 3188

EAB) (1725)

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:39
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

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 ☒

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:35
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:18

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 AUG 2020 16:18

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 AUG 2020 16:18

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 16:18
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3212004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	08:43 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:43
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 10:23 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 10:23

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

US3212004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 31 AUG 2020

Collection time (00:00-23:59) 09:29 (24 HR)

Collection date and time (derived) 31 AUG 2020 09:29

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:25	31 AUG 2020 09:25
Nasopharyngeal Swab 2	No		

US3212004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 31 AUG 2020 10:58

PC Open Date & Time 31 AUG 2020 10:43

PC Close Date & Time 31 AUG 2020 13:13

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp 01 SEP 2020 10:49

PC Open Date & Time 31 AUG 2020 14:08

PC Close Date & Time 01 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

01 SEP 2020 22:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 17:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:37

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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

31 AUG 2020 10:58

PC Open Date & Time

31 AUG 2020 10:43

PC Close Date & Time

31 AUG 2020 13:13

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 10:49

PC Open Date & Time

31 AUG 2020 14:08

PC Close Date & Time

01 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 17:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 21:37

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:46

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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 ☐

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 10:58
PC Open Date & Time	31 AUG 2020 10:43
PC Close Date & Time	31 AUG 2020 13:13

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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 ☐

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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

No ☒

Yes ☐

PC Time stamp 01 SEP 2020 10:49

PC Open Date & Time 31 AUG 2020 14:08

PC Close Date & Time 01 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

103 of 3188

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

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 ☒

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 3188

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 17:04
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

109 of 3188

EAB) (1725)

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 3188

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:55
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

113 of 3188

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3212004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

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

Visit date (dd MMM yyyy)	28 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:12 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:12
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3212004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

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

Collection date (dd MMM yyyy)	28 SEP 2020
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Collection time (00:00-23:59)	09:53 (24 HR)
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Collection date and time (derived)	28 SEP 2020 09:53
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US3212004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:29

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

03 OCT 2020 08:06:59

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

10 OCT 2020 11:17:37

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

17 OCT 2020 01:49:13

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

31 OCT 2020 09:48:37

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 07:20:26
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

14 NOV 2020 01:19:47

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

20 NOV 2020 18:36:46

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

25 NOV 2020 07:23:45

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 DEC 2020 08:05:13
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this 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	09 DEC 2020 03:46:21
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

16 DEC 2020 05:16:34

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 20:51:00

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

30 DEC 2020 00:02:00

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

06 JAN 2021 08:18:47

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

13 JAN 2021 00:33:44

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

20 JAN 2021 08:53:22

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

27 JAN 2021 07:37:02

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 08:00:06

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

10 FEB 2021 06:43:00

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

24 FEB 2021 07:53:42

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 MAR 2021 15:47:27
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

10 MAR 2021 00:19:20

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

17 MAR 2021 00:01:45

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

24 MAR 2021 06:50:25

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

07 APR 2021 14:44:42

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

28 APR 2021 00:01:33

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Patient Cloud Open Date & Time	18 AUG 2021 00:01
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Patient Cloud Close Date & Time	22 AUG 2021 23:59
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US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 411

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 621

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 754

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

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3212004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:42:51

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		02 MAR 2021 18:26:51

US3212004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:30

Generated On: 09 Jun 2021 15:42:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 12:44
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:30

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:30

Generated On: 09 Jun 2021 15:42:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	02 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:40 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	02 MAR 2021 13:40
------------------------------------	-------------------

US3212004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:30

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 19:00:58

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 19:00:58

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 APR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Date of Contact	02 DEC 2020
Time of Contact	10:19
Date and Time of Contact (derived)	02 DEC 2020 10:19
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	99.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

349 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Data signed: (ivalika2) 20 Apr 2021 18:37:21

Generated On: 09 Jun 2021 15:42:51

Date of Visit 02 DEC 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 04 DEC 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

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 18:44:03

Generated On: 09 Jun 2021 15:42:51

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 18:44:03

Generated On: 09 Jun 2021 15:42:51

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 18:44:03

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Data signed: (ivalika2) 09 Apr 2021 14:14:01

Generated On: 09 Jun 2021 15:42:51

Date of Contact	02 DEC 2020
Time of Contact	10:19
Date and Time of Contact (derived)	02 DEC 2020 10:19
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Data signed: (ivalika2) 16 Apr 2021 18:57:10

Generated On: 09 Jun 2021 15:42:51

Date of Visit	02 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	02 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Date of Contact	11 DEC 2020
Time of Contact	11:49
Date and Time of Contact (derived)	11 DEC 2020 11:49
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input checked="" type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

381 of 3188

EAB) (1725)

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

385 of 3188

EAB) (1725)

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.5 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

401 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

405 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

409 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 06 Apr 2021 14:50:59

Generated On: 09 Jun 2021 15:42:51

Date of Visit	11 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	07 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	HCA TOMBALL
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

413 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

414 of 3188

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 DEC 2020
Day 5	Yes	11 DEC 2020
Day 7	Yes	13 DEC 2020
Day 9	Yes	15 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 DEC 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 DEC 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	02 DEC 2020 10:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 17:21:15

Generated On: 09 Jun 2021 15:42:51

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 DEC 2020

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

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 SICKD1

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

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) _____

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

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.

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

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

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

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) _____

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

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.

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

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 _____

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

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.

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
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US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 02 MAR 2021

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☒

Folder OID UNBLND_DECIDE

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Date of updated informed consent (<i>dd MMM yyyy</i>)	02 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	02 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 12:44
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	14:28 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 14:28
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

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) 02 MAR 2021

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 13:43

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

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 18:44:03

Generated On: 09 Jun 2021 15:42:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	02 MAR 2021
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Collection time (00:00-23:59)	13:40 (24 HR)
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Collection date and time (derived)	02 MAR 2021 13:40
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US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	02 MAR 2021
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Collection time (00:00 - 23:59)	13:35
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Collection Date and Time (derived)	02 MAR 2021 13:35
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US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:16

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:21:17

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3212004

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:16:53

Generated On: 09 Jun 2021 15:42:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 14:16:54

Generated On: 09 Jun 2021 15:42:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 APR 2021
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 08:36
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 14:16:54

Generated On: 09 Jun 2021 15:42:51

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	02 APR 2021
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 11:35
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3212004

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:16:53

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212004

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 14:16:53

Generated On: 09 Jun 2021 15:42:51

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) 02 APR 2021

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 02 APR 2021 11:00

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

US3212004

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:16:53

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (ivalika2) 16 Apr 2021 18:57:10

Generated On: 09 Jun 2021 15:42:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212004

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (ivalika2) 16 Apr 2021 18:57:10

Generated On: 09 Jun 2021 15:42:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212004

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	27 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 APR 2021
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 08:42
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212004

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212004

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	27 APR 2021
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Collection time (00:00-23:59)	09:50 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	27 APR 2021 09:50
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US3212004

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

AEID

Adverse event

FATIGUE (REACTOGENICITY)

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)

11 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

PRODUCTION RELEASE (v12.003

459 of 3188

EAB) (1725)

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

AEID

Adverse event

MYALGIA
(REACTOGENICITY)

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)

11 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

PRODUCTION RELEASE (v12.003

461 of 3188

EAB) (1725)

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

AEID

Adverse event

ARTHRALGIA
(REACTOGENICITY)

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) 11 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

463 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

AEID	USA-US115-2020-MRNA-1273-P30 1000015
Adverse event	COVID 19 (PNEUMONIA)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	10 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

465 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

SHE HAS A HISTORY OF MILD
ASTHMA. SHE WAS HAVING
TELEHEALTH VISITS
RECENTLY WHEN SHE
DEVELOPED DYSPNEA AND
DIFFICULTY BREATHING. SHE
WENT TO THE ER AND SHE
TESTED POSITIVE FOR COVID
19. SHE HAD AN ABNORMAL
CT CHEST. SHE WAS ADMITTED
TO THE HOSPITAL AND
STARTED ON REMDESIVIR.
WILL FOLLOW HER AND
REQUEST RECORDS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

AEID

Adverse event

ELEVATED LFTS

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 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)

05 APR 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

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

468 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

AEID	
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	1 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	10 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

470 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

SHE HAS A HISTORY OF MILD
ASTHMA. SHE WAS HAVING
TELEHEALTH VISITS
RECENTLY WHEN SHE
DEVELOPED DYSPNEA AND
DIFFICULTY BREATHING. SHE
WENT TO THE ER AND SHE
TESTED POSITIVE FOR COVID
19. SHE HAD AN ABNORMAL CT
CHEST. SHE WAS ADMITTED TO
THE HOSPITAL AND STARTED
ON REMDESIVIR. WILL
FOLLOW HER AND REQUEST
RECORDS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 17:21:14

Generated On: 09 Jun 2021 15:42:51

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication FLUTICASONE
FUROATE/VILANTEROL

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 200/25

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

474 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication ETHINYLESTRADIOL/LEVONOR
GESTREL

Prophylaxis Yes ☐
No ☒

Indication MENORRHAGIA

Dose per administration 0.03/0.15

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

476 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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)

478 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

480 of 3188

EAB) (1725)

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication NYQUIL COLD & FLU
(ACETAMINOPHEN
500MG/DOXYLAMINE
SUCCINATE
6.25MG/DEXTROMETHORPHAN
HBR 15MG PER 15ML)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 30

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

482 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

484 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 4

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

1.5 TABLETS DAILY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

486 of 3188

EAB) (1725)

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication IV DECADRON

Prophylaxis Yes ☐
No ☒

Indication COVID19 (PNEUMONIA)

Dose per administration 6

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)

488 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 DEC 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

Name of Medication IV REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID19 (PNEUMONIA)

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

490 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:23:19

Generated On: 09 Jun 2021 15:42:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 DEC 2020	CT CHEST WITH CONTRAST	Adverse Event	

US3212004

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:42:51

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3212004

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:42:51

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 ☐

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3212004

Folder: SAE-USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/DEC/2020 13:32
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

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/DEC/2020 11:39
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

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/DEC/2020 13:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212004

Folder: SAE-USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/DEC/2020 09:44
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

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/DEC/2020 10:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/DEC/2020 14:23
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

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/DEC/2020 16:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Data signed: (b) (4) 01 Apr 2021 19:16:30

Generated On: 09 Jun 2021 15:42:51

SAEID	USA-US115-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/APR/2021 05:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3212004 (Prod: DM Clinical Research - ERN - PPDS)

US3212004

Form: Participant Creation

Generated On: 09 Jun 2021 15:42:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'US3212004'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:59:28

US3212004

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:13:20

US3212004

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:59:29

US3212004

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Clinic (Clinic)'	Nirja Shah (b) (4)	03 Aug 2020 16:13:20

US3212004

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'SCRN'	System	03 Aug 2020 16:13:20

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered (b) (6) 1982'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:59:30

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '38'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'YEARS'	System	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '38'	System	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Female (F)'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'I'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:13:53

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Aug 2020'	System	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2020'	System	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Amendment 1 (1)'	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:14:19

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:59:29

US3212004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'I'	System	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:42:51

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:42:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:14:56

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 02:34:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 02:34:43
Data point term sent to Coder	System	01 Sep 2020 02:33:35
Coding entries removed.	Afifah Ayub (b) (4)	01 Sep 2020 02:32:59
User entered 'mild ASTHMA' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Sep 2020 02:32:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 16:16:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 16:16:10
Data point term sent to Coder	System	03 Aug 2020 16:15:22
User entered 'Asthma'	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN UNK 2013'	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Jan 2013'	System	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2013'	System	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered empty.	System	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered empty.	System	03 Aug 2020 16:15:13

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Lip therapeutic procedures, PT: Lip repair, LLT: Cheiloplasty - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:17:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:17:11
Data point term sent to Coder	System	03 Aug 2020 16:16:23
User entered 'Cheiloplasty'	Nirja Shah (b) (4)	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		03 Aug 2020 16:16:27
User entered 'UN (b) (6) 1982' reason for change: Data Entry Error	Nirja Shah (b) (4)	03 Aug 2020 16:16:27
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	03 Aug 2020 16:15:55
User entered 'UN UNK 1982'	System	03 Aug 2020 16:15:55
	Nirja Shah (b) (4)	03 Aug 2020 16:15:55
	(b) (4)	

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	03 Aug 2020 16:16:34
User entered 'UN (b) (6) 1982' reason for change: Data Entry Error	Nirja Shah (b) (4)	03 Aug 2020 16:16:34
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	03 Aug 2020 16:16:27
User entered 'UN UNK 1982'	Nirja Shah (b) (4)	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '(b) (6) 1982'	System	03 Aug 2020 16:16:27
User entered 'Jan 1982'	System	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '(b) (6) 1982'	System	03 Aug 2020 16:16:34
User entered 'Jan 1982'	System	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	03 Aug 2020 16:15:55

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Palatal therapeutic procedures, PT: Palatoplasty, LLT: Palatoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:18:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:18:02
Data point term sent to Coder	System	03 Aug 2020 16:17:24
User entered 'Palatoplasty'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN (b) (6) 1982'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN (b) (6) 1982'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered (b) (6) 1982'	System	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered (b) (6) 1982'	System	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	03 Aug 2020 16:17:02

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:19:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:19:04
Data point term sent to Coder	System	03 Aug 2020 16:18:25
User entered 'Bilateral tubal ligation'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Aug 2004'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Aug 2004'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Aug 2004'	System	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2004'	System	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Aug 2004'	System	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2004'	System	03 Aug 2020 16:17:32

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:19:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 16:19:04
Data point term sent to Coder	System	03 Aug 2020 16:18:25
User entered 'Menorrhagia'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN UNK 2004'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN UNK 2017'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Jan 2004'	System	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2004'	System	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Jan 2017'	System	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '2017'	System	03 Aug 2020 16:17:58

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of face, neck and jaw congenital, PT: Cleft lip, LLT: Cleft lip - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:35:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:35:42
Data point term sent to Coder	System	01 Sep 2020 02:34:35
User entered 'Cleft Lip'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered (b) (6) 1982'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 02:36:50
User entered 'UN Dec 1982' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Sep 2020 02:36:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 02:36:29
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	01 Sep 2020 02:36:29
User entered ' Dec 1982' (non-conformant).	Afifah Ayub (b) (4)	01 Sep 2020 02:36:29
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	01 Sep 2020 02:34:08
User entered 'Un UNK 1982'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered (b) (6) 1982'	System	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Dec 1982'	System	01 Sep 2020 02:36:50
User entered empty.	System	01 Sep 2020 02:36:29
User entered 'Jan 1982'	System	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	01 Sep 2020 02:36:50
User entered empty.	System	01 Sep 2020 02:36:29
User entered '1982'	System	01 Sep 2020 02:34:08

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Gastrointestinal tract disorders congenital, HLT: Palate disorders congenital, PT: Cleft palate, LLT: Cleft palate - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:38:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 02:38:37
Data point term sent to Coder	System	01 Sep 2020 02:37:38
User entered 'Cleft Palate'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN (b) (6) 1982'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'UN Dec 1982'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered (b) (6) 1982'	System	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'Dec 1982'	System	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '1982'	System	01 Sep 2020 02:37:18

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '09:57'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered '03 Aug 2020 09:57'	System	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '67' in	Nirja Shah (b) (4)	03 Aug 2020 16:19:28
DataPoint set to visible.	(b) (4) System	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '205' lb	Nirja Shah (b) (4)	03 Aug 2020 16:19:28
DataPoint set to visible.	(b) (4) System	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
Amendment Manager: User entered '32.17467'	System	16 Sep 2020 23:41:12
User entered '32.2'	System	03 Aug 2020 16:19:28
DataPoint set to visible.	System	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'kg/m2'	System	03 Aug 2020 16:19:28
DataPoint set to visible.	System	03 Aug 2020 16:14:34

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered '97.7' F	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:00:48
User entered 'Other (Other)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered 'Oral (Oral)'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered '63'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'bpm'	System	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered '14'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'breaths/min'	System	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered '127'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'mmHg'	System	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done; reason for change Data Entry Error	afifah Ayub (b) (4)	19 Aug 2020 14:31:10
User entered '85'	Nirja Shah (b) (4)	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User entered 'mmHg'	System	03 Aug 2020 16:19:28

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14

US3212004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14

US3212004

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:19:49

US3212004

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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 09:24:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 13:41:57
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:19:49

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Aug 2020 16:21:35
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Aug 2020 16:21:21
User entered 'Surgically sterile (SURGICALLY STERILE)'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Aug 2004'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty; reason for change Data Entry Error	Nirja Shah (b) (4)	03 Aug 2020 16:21:35
User entered '08 Jul 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:42:51

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:21:21

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

[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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

[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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Business development manager'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

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 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'I'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:59:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Participant goes to their main workplace more than 2 days/week; interacts with 5 or more people during the course of a typical workday; Lives with school aged children & with someone in high risk job'	Nirja Shah (b) (4)	03 Aug 2020 16:24:28

US3212004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:41:32

US3212004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:41:32

US3212004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Clinic (Clinic)'	Nirja Shah (b) (4)	03 Aug 2020 16:41:32

US3212004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'VISIT1'	System	03 Aug 2020 16:41:32

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Aug 2020 16:04:19

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:44:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:44:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 16:04:19
User entered '100679' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Aug 2020 16:04:19

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Aug 2020 16:04:19

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:26

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:26

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:26

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:26

US3212004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:26

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:44:36
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '09:57' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:44:36
User entered '9:57'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '03 Aug 2020 09:57'	System	11 Dec 2020 14:44:36
User entered '3 Aug 2020 9:57'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '97.7' F	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '63'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'bpm'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '14'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'breaths/min'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '127'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '85'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:44:36
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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)	20 Aug 2020 15:22:14
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)	19 Aug 2020 14:34:32
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 14:33:56
User entered '12:23'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '03 Aug 2020 12:23'	System	11 Dec 2020 14:44:36
User entered '3 Aug 2020 12:23'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '97.7' F	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '75'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'bpm'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:48:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Aug 2020 15:48:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	27 Aug 2020 15:48:37
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 14:33:56
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'breaths/min'	System	27 Aug 2020 15:48:37
User entered empty.	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '142'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '91'	Afifah Ayub (b) (4)	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	19 Aug 2020 14:33:56

US3212004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Nirja Shah (b) (4)	03 Aug 2020 16:42:47

US3212004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:42:47

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '11:41'	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '03 Aug 2020 11:41'	System	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Left Arm (LEFT ARM)'	Nirja Shah (b) (4)	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'ONCE'	System	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 16:43:29

US3212004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	03 Aug 2020 18:11:51

US3212004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:44:48
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	03 Aug 2020 18:11:51

US3212004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '11:24'	Afifah Ayub (b) (4)	03 Aug 2020 18:11:51

US3212004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '03 Aug 2020 11:24'	System	11 Dec 2020 14:44:48
User entered '3 Aug 2020 11:24'	System	03 Aug 2020 18:11:51

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:42:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:44:56
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	03 Aug 2020 18:14:53
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Aug 2020 18:14:53
User entered '3 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Aug 2020 18:14:53
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	03 Aug 2020 18:12:19
User entered empty.	Afifah Ayub (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '11:20'	Afifah Ayub (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '03 Aug 2020 11:20'	System	11 Dec 2020 14:44:56
User entered '3 Aug 2020 11:20'	System	03 Aug 2020 18:14:53
User entered empty.	System	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:44:40
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:44:40
User entered '11:20'	Afifah Ayub (b) (4)	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered empty.	System	25 Aug 2020 19:44:40
User entered '3 Aug 2020 11:20'	System	03 Aug 2020 18:14:53
User entered empty.	System	03 Aug 2020 18:12:19

US3212004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 19:21:11

US3212004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '1'	System	18 Aug 2020 19:21:11

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:25', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4f725de4-20b1-4023-9817-6598b50501d8'	System	03 Aug 2020 17:22:41
User entered 'Yes (Y)'	System	03 Aug 2020 17:22:41

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4f725de4-20b1-4023-9817-6598b50501d8'	System	03 Aug 2020 17:22:41
User entered '97.7'	System	03 Aug 2020 17:22:41

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4f725de4-20b1-4023-9817-6598b50501d8'	System	03 Aug 2020 17:22:41
User entered 'No (N)'	System	03 Aug 2020 17:22:41

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4f725de4-20b1-4023-9817-6598b50501d8'	System	03 Aug 2020 17:22:41
User entered '03 Aug 2020 12:22'	System	03 Aug 2020 17:22:41

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 12:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 14:31'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T18:59:48', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '877495ae-5ea0-401d-af76-be994bfe147c'	System	04 Aug 2020 00:01:47
User entered 'Yes (Y)'	System	04 Aug 2020 00:01:47

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:28', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '877495ae-5ea0-401d-af76-be994bfe147c'	System	04 Aug 2020 00:01:47
User entered '98.8'	System	04 Aug 2020 00:01:47

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '877495ae-5ea0-401d-af76-be994bfe147c'	System	04 Aug 2020 00:01:47
User entered 'No (N)'	System	04 Aug 2020 00:01:47

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '877495ae-5ea0-401d-af76-be994bfe147c'	System	04 Aug 2020 00:01:47
User entered '03 Aug 2020 19:01'	System	04 Aug 2020 00:01:47

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 15:26'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 2'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:03:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '8d266d66-55ca-4f43-802f-f426f1af4270'	System	04 Aug 2020 22:04:09
User entered 'Yes (Y)'	System	04 Aug 2020 22:04:09

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '8d266d66-55ca-4f43-802f-f426f1af4270'	System	04 Aug 2020 22:04:09
User entered '98.1'	System	04 Aug 2020 22:04:09

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '8d266d66-55ca-4f43-802f-f426f1af4270'	System	04 Aug 2020 22:04:09
User entered 'No (N)'	System	04 Aug 2020 22:04:09

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '8d266d66-55ca-4f43-802f-f426f1af4270'	System	04 Aug 2020 22:04:09
User entered '04 Aug 2020 17:04'	System	04 Aug 2020 22:04:09

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 3'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2815100d-33a5-4b4d-a113-137c7aecdb97'	System	05 Aug 2020 23:13:25
User entered 'Yes (Y)'	System	05 Aug 2020 23:13:25

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2815100d-33a5-4b4d-a113-137c7aecdb97'	System	05 Aug 2020 23:13:25
User entered '97.5'	System	05 Aug 2020 23:13:25

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2815100d-33a5-4b4d-a113-137c7aecdb97'	System	05 Aug 2020 23:13:25
User entered 'No (N)'	System	05 Aug 2020 23:13:25

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:21', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2815100d-33a5-4b4d-a113-137c7aecdb97'	System	05 Aug 2020 23:13:25
User entered '05 Aug 2020 18:13'	System	05 Aug 2020 23:13:25

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 4'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:45:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2b09c5c1-36f2-40b2-9b8e-0e3c83d9edb3'	System	07 Aug 2020 01:45:52
User entered 'Yes (Y)'	System	07 Aug 2020 01:45:52

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:45:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2b09c5c1-36f2-40b2-9b8e-0e3c83d9edb3' User entered '98.2'	System	07 Aug 2020 01:45:52

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:45:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2b09c5c1-36f2-40b2-9b8e-0e3c83d9edb3'	System	07 Aug 2020 01:45:52
User entered 'No (N)'	System	07 Aug 2020 01:45:52

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:45:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2b09c5c1-36f2-40b2-9b8e-0e3c83d9edb3'	System	07 Aug 2020 01:45:52
User entered '06 Aug 2020 20:45'	System	07 Aug 2020 01:45:52

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 5'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f8b3a169-d637-478d-b970-d1f84d29668f'	System	07 Aug 2020 23:42:12
User entered 'Yes (Y)'	System	07 Aug 2020 23:42:12

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f8b3a169-d637-478d-b970-d1f84d29668f' User entered '97.9'	System	07 Aug 2020 23:42:12

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:07', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f8b3a169-d637-478d-b970-d1f84d29668f'	System	07 Aug 2020 23:42:12
User entered 'No (N)'	System	07 Aug 2020 23:42:12

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f8b3a169-d637-478d-b970-d1f84d29668f'	System	07 Aug 2020 23:42:12
User entered '07 Aug 2020 18:42'	System	07 Aug 2020 23:42:12

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 6'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:01', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '92ce3134-c718-48d0-a848-cdc1b1c6f3bf'	System	08 Aug 2020 19:39:16
User entered 'Yes (Y)'	System	08 Aug 2020 19:39:16

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '92ce3134-c718-48d0-a848-cdc1b1c6f3bf' User entered '98.0'	System	08 Aug 2020 19:39:16

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '92ce3134-c718-48d0-a848-cdc1b1c6f3bf'	System	08 Aug 2020 19:39:16
User entered 'No (N)'	System	08 Aug 2020 19:39:16

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:12', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '92ce3134-c718-48d0-a848-cdc1b1c6f3bf'	System	08 Aug 2020 19:39:16
User entered '08 Aug 2020 14:39'	System	08 Aug 2020 19:39:16

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 7'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:36:07', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd9258503-253c-4aba-b876-dbd59dba217c'	System	10 Aug 2020 00:36:19
User entered 'Yes (Y)'	System	10 Aug 2020 00:36:19

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:36:11', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd9258503-253c-4aba-b876-dbd59dba217c'	System	10 Aug 2020 00:36:19
User entered '97.7'	System	10 Aug 2020 00:36:19

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:36:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd9258503-253c-4aba-b876-dbd59dba217c'	System	10 Aug 2020 00:36:19
User entered 'No (N)'	System	10 Aug 2020 00:36:19

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:36:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd9258503-253c-4aba-b876-dbd59dba217c'	System	10 Aug 2020 00:36:19
User entered '09 Aug 2020 19:36'	System	10 Aug 2020 00:36:19

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:50', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eeace552-1357-4db5-93bc-3d7537f0929b'	System	03 Aug 2020 17:23:15
User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 17:23:15

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:22:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eeace552-1357-4db5-93bc-3d7537f0929b'	System	03 Aug 2020 17:23:15
User entered 'No (N)'	System	03 Aug 2020 17:23:15

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eeace552-1357-4db5-93bc-3d7537f0929b'	System	03 Aug 2020 17:23:15
User entered 'No (N)'	System	03 Aug 2020 17:23:15

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eeace552-1357-4db5-93bc-3d7537f0929b'	System	03 Aug 2020 17:23:15
User entered 'None (1)'	System	03 Aug 2020 17:23:15

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:12', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eeace552-1357-4db5-93bc-3d7537f0929b'	System	03 Aug 2020 17:23:15
User entered '03 Aug 2020 12:23'	System	03 Aug 2020 17:23:15

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 12:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 14:31'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:50', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6da3713d-4729-45df-816e-fc8dfe07765a'	System	04 Aug 2020 00:02:12
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 00:02:12

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:53', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6da3713d-4729-45df-816e-fc8dfe07765a'	System	04 Aug 2020 00:02:12
User entered 'No (N)'	System	04 Aug 2020 00:02:12

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:01:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6da3713d-4729-45df-816e-fc8dfe07765a'	System	04 Aug 2020 00:02:12
User entered 'No (N)'	System	04 Aug 2020 00:02:12

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6da3713d-4729-45df-816e-fc8dfe07765a'	System	04 Aug 2020 00:02:12
User entered 'None (1)'	System	04 Aug 2020 00:02:12

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6da3713d-4729-45df-816e-fc8dfe07765a'	System	04 Aug 2020 00:02:12
User entered '03 Aug 2020 19:02'	System	04 Aug 2020 00:02:12

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 15:26'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 2'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd6784242-cda0-45e4-8657-9fc658ac4563'	System	04 Aug 2020 22:04:48
User entered 'None (1)'	System	04 Aug 2020 22:04:48

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd6784242-cda0-45e4-8657-9fc658ac4563'	System	04 Aug 2020 22:04:48
User entered 'No (N)'	System	04 Aug 2020 22:04:48

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd6784242-cda0-45e4-8657-9fc658ac4563'	System	04 Aug 2020 22:04:48
User entered 'No (N)'	System	04 Aug 2020 22:04:48

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:23', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd6784242-cda0-45e4-8657-9fc658ac4563'	System	04 Aug 2020 22:04:48
User entered 'None (1)'	System	04 Aug 2020 22:04:48

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd6784242-cda0-45e4-8657-9fc658ac4563'	System	04 Aug 2020 22:04:48
User entered '04 Aug 2020 17:04'	System	04 Aug 2020 22:04:48

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 3'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7e6c705d-5aca-4fb7-aa1b-fc98d7ec6d41'	System	05 Aug 2020 23:13:38
User entered 'None (1)'	System	05 Aug 2020 23:13:38

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:28', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7e6c705d-5aca-4fb7-aa1b-fc98d7ec6d41'	System	05 Aug 2020 23:13:38
User entered 'No (N)'	System	05 Aug 2020 23:13:38

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7e6c705d-5aca-4fb7-aa1b-fc98d7ec6d41'	System	05 Aug 2020 23:13:38
User entered 'No (N)'	System	05 Aug 2020 23:13:38

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7e6c705d-5aca-4fb7-aa1b-fc98d7ec6d41'	System	05 Aug 2020 23:13:38
User entered 'None (1)'	System	05 Aug 2020 23:13:38

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7e6c705d-5aca-4fb7-aa1b-fc98d7ec6d41'	System	05 Aug 2020 23:13:38
User entered '05 Aug 2020 18:13'	System	05 Aug 2020 23:13:38

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 4'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:45:56', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '217c59ce-6ada-4247-b1b5-3b00ae8755fd'	System	07 Aug 2020 01:46:09
User entered 'None (1)'	System	07 Aug 2020 01:46:09

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '217c59ce-6ada-4247-b1b5-3b00ae8755fd'	System	07 Aug 2020 01:46:09
User entered 'No (N)'	System	07 Aug 2020 01:46:09

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:03', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '217c59ce-6ada-4247-b1b5-3b00ae8755fd'	System	07 Aug 2020 01:46:09
User entered 'No (N)'	System	07 Aug 2020 01:46:09

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '217c59ce-6ada-4247-b1b5-3b00ae8755fd'	System	07 Aug 2020 01:46:09
User entered 'None (1)'	System	07 Aug 2020 01:46:09

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '217c59ce-6ada-4247-b1b5-3b00ae8755fd'	System	07 Aug 2020 01:46:09
User entered '06 Aug 2020 20:46'	System	07 Aug 2020 01:46:09

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 5'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15485fef-665d-40c9-bb5d-1620e226f658'	System	07 Aug 2020 23:42:29
User entered 'None (1)'	System	07 Aug 2020 23:42:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15485fef-665d-40c9-bb5d-1620e226f658'	System	07 Aug 2020 23:42:29
User entered 'No (N)'	System	07 Aug 2020 23:42:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15485fef-665d-40c9-bb5d-1620e226f658'	System	07 Aug 2020 23:42:29
User entered 'No (N)'	System	07 Aug 2020 23:42:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:23', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15485fef-665d-40c9-bb5d-1620e226f658'	System	07 Aug 2020 23:42:29
User entered 'None (1)'	System	07 Aug 2020 23:42:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15485fef-665d-40c9-bb5d-1620e226f658'	System	07 Aug 2020 23:42:29
User entered '07 Aug 2020 18:42'	System	07 Aug 2020 23:42:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 6'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '052d4001-01d1-45ea-b1b2-9a46ab6c512c'	System	08 Aug 2020 19:39:31
User entered 'None (1)'	System	08 Aug 2020 19:39:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:19', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '052d4001-01d1-45ea-b1b2-9a46ab6c512c'	System	08 Aug 2020 19:39:31
User entered 'No (N)'	System	08 Aug 2020 19:39:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '052d4001-01d1-45ea-b1b2-9a46ab6c512c' User entered 'No (N)'	System	08 Aug 2020 19:39:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '052d4001-01d1-45ea-b1b2-9a46ab6c512c'	System	08 Aug 2020 19:39:31
User entered 'None (1)'	System	08 Aug 2020 19:39:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '052d4001-01d1-45ea-b1b2-9a46ab6c512c'	System	08 Aug 2020 19:39:31
User entered '08 Aug 2020 14:39'	System	08 Aug 2020 19:39:31

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 7'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:34:48', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ebc4e436-eade-4af4-92b1-0569b3c4fcb7'	System	10 Aug 2020 00:35:04
User entered 'None (1)'	System	10 Aug 2020 00:35:04

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:34:52', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ebc4e436-eade-4af4-92b1-0569b3c4fcb7'	System	10 Aug 2020 00:35:04
User entered 'No (N)'	System	10 Aug 2020 00:35:04

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:34:53', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ebc4e436-eade-4af4-92b1-0569b3c4fcb7'	System	10 Aug 2020 00:35:04
User entered 'No (N)'	System	10 Aug 2020 00:35:04

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:34:55', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ebc4e436-eade-4af4-92b1-0569b3c4fcb7'	System	10 Aug 2020 00:35:04
User entered 'None (1)'	System	10 Aug 2020 00:35:04

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:34:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ebc4e436-eade-4af4-92b1-0569b3c4fcb7'	System	10 Aug 2020 00:35:04
User entered '09 Aug 2020 19:34'	System	10 Aug 2020 00:35:04

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'None (0)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered 'No (N)'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T12:23:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4445b8d1-839a-4b74-b280-0212d408c871'	System	03 Aug 2020 17:23:53
User entered '03 Aug 2020 12:23'	System	03 Aug 2020 17:23:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 12:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 14:31'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:19', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:21', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:25', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'None (0)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:27', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered 'No (N)'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-03T19:02:30', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'dc9c0d85-de9a-41f7-a100-62bb2a4c0a07'	System	04 Aug 2020 00:02:34
User entered '03 Aug 2020 19:02'	System	04 Aug 2020 00:02:34

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Aug 2020 15:26'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 2'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:51', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:55', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:04:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:05:03', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:05:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'None (0)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:05:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered 'No (N)'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-04T17:05:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f7d06715-c4a7-4c06-8aae-9f33aba48d46'	System	04 Aug 2020 22:05:13
User entered '04 Aug 2020 17:05'	System	04 Aug 2020 22:05:13

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 3'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:50', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:52', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'None (0)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:13:59', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered 'No (N)'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-05T18:14:01', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '534156fd-286b-49cc-9fd8-b6a2653736bb'	System	05 Aug 2020 23:14:03
User entered '05 Aug 2020 18:14'	System	05 Aug 2020 23:14:03

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 4'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:12', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:17', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:23', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'None (0)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:27', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered 'No (N)'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-06T20:46:29', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ceba44d8-236c-410e-9515-a16c56811752'	System	07 Aug 2020 01:46:31
User entered '06 Aug 2020 20:46'	System	07 Aug 2020 01:46:31

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 5'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:29', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:42', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'None (0)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered 'No (N)'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-07T18:42:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ff169f1e-1390-4d31-a704-109e5dfec162'	System	07 Aug 2020 23:42:51
User entered '07 Aug 2020 18:42'	System	07 Aug 2020 23:42:51

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 6'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'None (0)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered 'No (N)'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-08T14:39:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'eaff9751-4312-48c6-b6ef-0761cb7e4a9c'	System	08 Aug 2020 19:39:53
User entered '08 Aug 2020 14:39'	System	08 Aug 2020 19:39:53

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 7'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'None (0)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:21', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'No interference with activity (1)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'No interference with activity (1)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'No interference with activity (1)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'None (0)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'None (0)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered 'No (N)'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-09T19:35:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '12277104-6b83-40b3-ba4b-0c6e0d999096'	System	10 Aug 2020 00:35:42
User entered '09 Aug 2020 19:35'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 8'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 9'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:01', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '83cada7b-a4f2-4adc-bd37-d066c96df69a'	System	11 Aug 2020 21:18:08
User entered 'None (0)'	System	11 Aug 2020 21:18:08

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:04', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '83cada7b-a4f2-4adc-bd37-d066c96df69a'	System	11 Aug 2020 21:18:08
User entered '11 Aug 2020 16:18'	System	11 Aug 2020 21:18:08

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 8'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 9'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5925c795-8b05-4a19-bcbe-e6e5c81515c1' User entered 'None (0)'	System	11 Aug 2020 21:18:13
	System	11 Aug 2020 21:18:13

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5925c795-8b05-4a19-bcbe-e6e5c81515c1'	System	11 Aug 2020 21:18:13
User entered '11 Aug 2020 16:18'	System	11 Aug 2020 21:18:13

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 8'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 9'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:11', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3808baae-2b94-46a4-82fd-16fd243244fb'	System	11 Aug 2020 21:18:18
User entered 'None (0)'	System	11 Aug 2020 21:18:18

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3808baae-2b94-46a4-82fd-16fd243244fb'	System	11 Aug 2020 21:18:18
User entered '11 Aug 2020 16:18'	System	11 Aug 2020 21:18:18

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 8'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	10 Aug 2020 00:35:42
User entered 'Day 9'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4fd00bee-4994-4607-b90c-46c13aaa7721'	System	11 Aug 2020 21:18:23
User entered 'No (N)'	System	11 Aug 2020 21:18:23

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-11T16:18:19', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4fd00bee-4994-4607-b90c-46c13aaa7721'	System	11 Aug 2020 21:18:23
User entered '11 Aug 2020 16:18'	System	11 Aug 2020 21:18:23

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 00:35:42

US3212004

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 00:35:42

US3212004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 19:49:18

US3212004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '10 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 19:49:18

US3212004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 19:49:18

US3212004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:49:18

US3212004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 19:49:21

US3212004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	18 Aug 2020 19:49:21

US3212004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 19:49:30

US3212004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '17 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 19:49:30

US3212004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 19:49:30

US3212004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:49:30

US3212004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:20

US3212004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	25 Aug 2020 15:02:20

US3212004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:32

US3212004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '24 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:32

US3212004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:32

US3212004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:32

US3212004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:02:40

US3212004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	25 Aug 2020 15:02:40

US3212004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 13:41:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 13:41:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	31 Aug 2020 13:41:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'VISIT2'	System	31 Aug 2020 13:41:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '08:43' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:45:16
User entered '8:43'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '31 Aug 2020 08:43'	System	11 Dec 2020 14:45:16
User entered '31 Aug 2020 8:43'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '97.7' F	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '71'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'bpm'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '15'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'breaths/min'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '134'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '85'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '11:00'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '31 Aug 2020 11:00'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '97.8' F	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '62'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'bpm'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '17'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'breaths/min'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '132'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '66'	Afifah Ayub (b) (4)	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	31 Aug 2020 16:35:57

US3212004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 14:14:50

US3212004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 14:14:50

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '10:23'	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '31 Aug 2020 10:23'	System	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'ONCE'	System	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:26:30

US3212004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:06

US3212004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:06

US3212004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '09:29' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:45:27
User entered '9:29'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:06

US3212004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '31 Aug 2020 09:29'	System	11 Dec 2020 14:45:27
User entered '31 Aug 2020 9:29'	System	31 Aug 2020 16:17:06

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '09:25' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:45:35
User entered '9:25'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '31 Aug 2020 09:25'	System	11 Dec 2020 14:45:35
User entered '31 Aug 2020 9:25'	System	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'No (N)'	Afifah Ayub (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered empty.	System	31 Aug 2020 16:17:20

US3212004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	31 Aug 2020 15:26:40

US3212004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	31 Aug 2020 15:26:40

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5a8b60e1-86fa-47f9-adbc-f87fbc3549ab'	System	31 Aug 2020 15:58:45
User entered 'Yes (Y)'	System	31 Aug 2020 15:58:45

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5a8b60e1-86fa-47f9-adbc-f87fbc3549ab' User entered '97.8'	System	31 Aug 2020 15:58:45

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5a8b60e1-86fa-47f9-adbc-f87fbc3549ab'	System	31 Aug 2020 15:58:45
User entered 'No (N)'	System	31 Aug 2020 15:58:45

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:12', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5a8b60e1-86fa-47f9-adbc-f87fbc3549ab'	System	31 Aug 2020 15:58:45
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 15:58:45

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 10:43'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 13:13'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:48:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd8264f24-4720-417c-8e9e-83bf07c36ce9'	System	01 Sep 2020 15:49:19
User entered 'Yes (Y)'	System	01 Sep 2020 15:49:19

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:11', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd8264f24-4720-417c-8e9e-83bf07c36ce9' User entered '98.3'	System	01 Sep 2020 15:49:19

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:14', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd8264f24-4720-417c-8e9e-83bf07c36ce9'	System	01 Sep 2020 15:49:19
User entered 'No (N)'	System	01 Sep 2020 15:49:19

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:17', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd8264f24-4720-417c-8e9e-83bf07c36ce9'	System	01 Sep 2020 15:49:19
User entered '01 Sep 2020 10:49'	System	01 Sep 2020 15:49:19

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 14:08'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 2'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6a81e046-9a5a-493c-9a4e-5a11f785dcc6'	System	02 Sep 2020 03:02:20
User entered 'Yes (Y)'	System	02 Sep 2020 03:02:20

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6a81e046-9a5a-493c-9a4e-5a11f785dcc6'	System	02 Sep 2020 03:02:20
User entered '98.6'	System	02 Sep 2020 03:02:20

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6a81e046-9a5a-493c-9a4e-5a11f785dcc6'	System	02 Sep 2020 03:02:20
User entered 'No (N)'	System	02 Sep 2020 03:02:20

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:17', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6a81e046-9a5a-493c-9a4e-5a11f785dcc6'	System	02 Sep 2020 03:02:20
User entered '01 Sep 2020 22:02'	System	02 Sep 2020 03:02:20

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 3'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:22:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cf08bc77-477c-44dc-808c-ac1b5edf75a4'	System	03 Sep 2020 01:23:44
User entered 'Yes (Y)'	System	03 Sep 2020 01:23:44

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:32', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cf08bc77-477c-44dc-808c-ac1b5edf75a4'	System	03 Sep 2020 01:23:44
User entered '98.5'	System	03 Sep 2020 01:23:44

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cf08bc77-477c-44dc-808c-ac1b5edf75a4'	System	03 Sep 2020 01:23:44
User entered 'No (N)'	System	03 Sep 2020 01:23:44

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cf08bc77-477c-44dc-808c-ac1b5edf75a4'	System	03 Sep 2020 01:23:44
User entered '02 Sep 2020 20:23'	System	03 Sep 2020 01:23:44

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 4'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '77e4f28a-a9f9-4e06-a024-280a124a7b60'	System	03 Sep 2020 22:04:15
User entered 'Yes (Y)'	System	03 Sep 2020 22:04:15

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '77e4f28a-a9f9-4e06-a024-280a124a7b60'	System	03 Sep 2020 22:04:15
User entered '98.5'	System	03 Sep 2020 22:04:15

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '77e4f28a-a9f9-4e06-a024-280a124a7b60'	System	03 Sep 2020 22:04:15
User entered 'No (N)'	System	03 Sep 2020 22:04:15

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '77e4f28a-a9f9-4e06-a024-280a124a7b60'	System	03 Sep 2020 22:04:15
User entered '03 Sep 2020 17:04'	System	03 Sep 2020 22:04:15

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 5'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:23', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '733525cc-b20f-44b1-ad46-cc0f27189a3c'	System	05 Sep 2020 02:37:34
User entered 'Yes (Y)'	System	05 Sep 2020 02:37:34

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:27', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '733525cc-b20f-44b1-ad46-cc0f27189a3c'	System	05 Sep 2020 02:37:34
User entered '98.1'	System	05 Sep 2020 02:37:34

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:29', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '733525cc-b20f-44b1-ad46-cc0f27189a3c'	System	05 Sep 2020 02:37:34
User entered 'No (N)'	System	05 Sep 2020 02:37:34

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '733525cc-b20f-44b1-ad46-cc0f27189a3c'	System	05 Sep 2020 02:37:34
User entered '04 Sep 2020 21:37'	System	05 Sep 2020 02:37:34

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 6'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:53:56', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52aa225d-8604-434d-a747-d3518052d325'	System	06 Sep 2020 00:54:38
User entered 'Yes (Y)'	System	06 Sep 2020 00:54:38

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:30', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52aa225d-8604-434d-a747-d3518052d325' User entered '98.8'	System	06 Sep 2020 00:54:38

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52aa225d-8604-434d-a747-d3518052d325'	System	06 Sep 2020 00:54:38
User entered 'No (N)'	System	06 Sep 2020 00:54:38

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52aa225d-8604-434d-a747-d3518052d325'	System	06 Sep 2020 00:54:38
User entered '05 Sep 2020 19:54'	System	06 Sep 2020 00:54:38

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 7'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:45:52', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f4936bad-2826-497b-8dc5-650310c7d954'	System	06 Sep 2020 23:46:01
User entered 'Yes (Y)'	System	06 Sep 2020 23:46:01

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:45:55', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f4936bad-2826-497b-8dc5-650310c7d954' User entered '98.5'	System	06 Sep 2020 23:46:01

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:45:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f4936bad-2826-497b-8dc5-650310c7d954'	System	06 Sep 2020 23:46:01
User entered 'No (N)'	System	06 Sep 2020 23:46:01

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:45:59', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f4936bad-2826-497b-8dc5-650310c7d954'	System	06 Sep 2020 23:46:01
User entered '06 Sep 2020 18:45'	System	06 Sep 2020 23:46:01

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:17', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'b2d44d96-ca6d-468e-abb0-1b256ea3d039'	System	31 Aug 2020 15:58:49
User entered 'None (1)'	System	31 Aug 2020 15:58:49

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:19', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'b2d44d96-ca6d-468e-abb0-1b256ea3d039'	System	31 Aug 2020 15:58:49
User entered 'No (N)'	System	31 Aug 2020 15:58:49

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'b2d44d96-ca6d-468e-abb0-1b256ea3d039'	System	31 Aug 2020 15:58:49
User entered 'No (N)'	System	31 Aug 2020 15:58:49

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'b2d44d96-ca6d-468e-abb0-1b256ea3d039'	System	31 Aug 2020 15:58:49
User entered 'None (1)'	System	31 Aug 2020 15:58:49

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'b2d44d96-ca6d-468e-abb0-1b256ea3d039'	System	31 Aug 2020 15:58:49
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 15:58:49

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 10:43'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 13:13'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e3757bf3-9c25-47aa-8f2c-cd9fd8571769'	System	01 Sep 2020 15:49:30
User entered 'None (1)'	System	01 Sep 2020 15:49:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e3757bf3-9c25-47aa-8f2c-cd9fd8571769'	System	01 Sep 2020 15:49:30
User entered 'No (N)'	System	01 Sep 2020 15:49:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e3757bf3-9c25-47aa-8f2c-cd9fd8571769'	System	01 Sep 2020 15:49:30
User entered 'No (N)'	System	01 Sep 2020 15:49:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:25', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e3757bf3-9c25-47aa-8f2c-cd9fd8571769'	System	01 Sep 2020 15:49:30
User entered 'None (1)'	System	01 Sep 2020 15:49:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:27', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e3757bf3-9c25-47aa-8f2c-cd9fd8571769'	System	01 Sep 2020 15:49:30
User entered '01 Sep 2020 10:49'	System	01 Sep 2020 15:49:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 14:08'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 2'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ede7b376-3643-484f-b465-5eb6cbf04d01'	System	02 Sep 2020 03:02:40
User entered 'None (1)'	System	02 Sep 2020 03:02:40

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ede7b376-3643-484f-b465-5eb6cbf04d01'	System	02 Sep 2020 03:02:40
User entered 'No (N)'	System	02 Sep 2020 03:02:40

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ede7b376-3643-484f-b465-5eb6cbf04d01'	System	02 Sep 2020 03:02:40
User entered 'No (N)'	System	02 Sep 2020 03:02:40

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ede7b376-3643-484f-b465-5eb6cbf04d01'	System	02 Sep 2020 03:02:40
User entered 'None (1)'	System	02 Sep 2020 03:02:40

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ede7b376-3643-484f-b465-5eb6cbf04d01'	System	02 Sep 2020 03:02:40
User entered '01 Sep 2020 22:02'	System	02 Sep 2020 03:02:40

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 3'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6c57911a-d067-46f8-a640-d3261b9e25d4'	System	03 Sep 2020 01:23:53
User entered 'None (1)'	System	03 Sep 2020 01:23:53

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6c57911a-d067-46f8-a640-d3261b9e25d4'	System	03 Sep 2020 01:23:53
User entered 'No (N)'	System	03 Sep 2020 01:23:53

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:48', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6c57911a-d067-46f8-a640-d3261b9e25d4'	System	03 Sep 2020 01:23:53
User entered 'No (N)'	System	03 Sep 2020 01:23:53

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6c57911a-d067-46f8-a640-d3261b9e25d4'	System	03 Sep 2020 01:23:53
User entered 'None (1)'	System	03 Sep 2020 01:23:53

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:51', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6c57911a-d067-46f8-a640-d3261b9e25d4'	System	03 Sep 2020 01:23:53
User entered '02 Sep 2020 20:23'	System	03 Sep 2020 01:23:53

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 4'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:14', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e6719768-6eb9-4b6f-bc44-0990dd3b6e12'	System	03 Sep 2020 22:04:24
User entered 'None (1)'	System	03 Sep 2020 22:04:24

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e6719768-6eb9-4b6f-bc44-0990dd3b6e12'	System	03 Sep 2020 22:04:24
User entered 'No (N)'	System	03 Sep 2020 22:04:24

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e6719768-6eb9-4b6f-bc44-0990dd3b6e12'	System	03 Sep 2020 22:04:24
User entered 'No (N)'	System	03 Sep 2020 22:04:24

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e6719768-6eb9-4b6f-bc44-0990dd3b6e12'	System	03 Sep 2020 22:04:24
User entered 'None (1)'	System	03 Sep 2020 22:04:24

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e6719768-6eb9-4b6f-bc44-0990dd3b6e12'	System	03 Sep 2020 22:04:24
User entered '03 Sep 2020 17:04'	System	03 Sep 2020 22:04:24

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 5'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd366da4c-fe4d-4687-8652-ceb2e31a710f'	System	05 Sep 2020 02:37:44
User entered 'None (1)'	System	05 Sep 2020 02:37:44

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd366da4c-fe4d-4687-8652-ceb2e31a710f'	System	05 Sep 2020 02:37:44
User entered 'No (N)'	System	05 Sep 2020 02:37:44

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd366da4c-fe4d-4687-8652-ceb2e31a710f'	System	05 Sep 2020 02:37:44
User entered 'No (N)'	System	05 Sep 2020 02:37:44

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd366da4c-fe4d-4687-8652-ceb2e31a710f'	System	05 Sep 2020 02:37:44
User entered 'None (1)'	System	05 Sep 2020 02:37:44

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd366da4c-fe4d-4687-8652-ceb2e31a710f'	System	05 Sep 2020 02:37:44
User entered '04 Sep 2020 21:37'	System	05 Sep 2020 02:37:44

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 6'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3e5345b8-b4b5-4c7c-80fe-dc89bd75865d'	System	06 Sep 2020 00:54:50
User entered 'None (1)'	System	06 Sep 2020 00:54:50

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3e5345b8-b4b5-4c7c-80fe-dc89bd75865d'	System	06 Sep 2020 00:54:50
User entered 'No (N)'	System	06 Sep 2020 00:54:50

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3e5345b8-b4b5-4c7c-80fe-dc89bd75865d'	System	06 Sep 2020 00:54:50
User entered 'No (N)'	System	06 Sep 2020 00:54:50

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3e5345b8-b4b5-4c7c-80fe-dc89bd75865d'	System	06 Sep 2020 00:54:50
User entered 'None (1)'	System	06 Sep 2020 00:54:50

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '3e5345b8-b4b5-4c7c-80fe-dc89bd75865d'	System	06 Sep 2020 00:54:50
User entered '05 Sep 2020 19:54'	System	06 Sep 2020 00:54:50

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 7'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cb2f4d0d-ca41-41b2-89a8-492dd175cd24'	System	06 Sep 2020 23:46:15
User entered 'None (1)'	System	06 Sep 2020 23:46:15

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:04', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cb2f4d0d-ca41-41b2-89a8-492dd175cd24'	System	06 Sep 2020 23:46:15
User entered 'No (N)'	System	06 Sep 2020 23:46:15

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cb2f4d0d-ca41-41b2-89a8-492dd175cd24'	System	06 Sep 2020 23:46:15
User entered 'No (N)'	System	06 Sep 2020 23:46:15

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:07', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cb2f4d0d-ca41-41b2-89a8-492dd175cd24'	System	06 Sep 2020 23:46:15
User entered 'None (1)'	System	06 Sep 2020 23:46:15

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'cb2f4d0d-ca41-41b2-89a8-492dd175cd24'	System	06 Sep 2020 23:46:15
User entered '06 Sep 2020 18:46'	System	06 Sep 2020 23:46:15

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:28', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:30', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'None (0)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered 'No (N)'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-08-31T10:58:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c9eb166b-64fe-444d-921f-5c3302911ccb'	System	31 Aug 2020 15:58:53
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 15:58:53

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 10:43'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 13:13'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:32', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'None (0)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered 'No (N)'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T10:49:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '2aa9aecc-6488-49e9-921d-1ed65fbb618e'	System	01 Sep 2020 15:49:47
User entered '01 Sep 2020 10:49'	System	01 Sep 2020 15:49:47

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '31 Aug 2020 14:08'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 2'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:42', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'None (0)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:50', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered 'No (N)'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-01T22:02:52', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e154b013-8a4c-40cc-a243-c22a17a1246e'	System	02 Sep 2020 03:02:54
User entered '01 Sep 2020 22:02'	System	02 Sep 2020 03:02:54

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 3'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:56', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:23:59', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94' User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:03', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'None (0)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:11', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered 'No (N)'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-02T20:24:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '58e1daa2-c822-492b-a99d-94cd9014ec94'	System	03 Sep 2020 01:24:24
User entered '02 Sep 2020 20:24'	System	03 Sep 2020 01:24:24

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 4'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:27', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:29', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:30', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:33', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'None (0)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:38', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered 'No (N)'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-03T17:04:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95625f78-2c24-4a49-94b9-6a6792367c74'	System	03 Sep 2020 22:04:45
User entered '03 Sep 2020 17:04'	System	03 Sep 2020 22:04:45

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 5'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:50', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:51', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'None (0)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered 'No (N)'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-04T21:37:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1f3edc4f-9ac9-43cf-83ee-a48f22d5565c'	System	05 Sep 2020 02:38:01
User entered '04 Sep 2020 21:37'	System	05 Sep 2020 02:38:01

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 6'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:51', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:54:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:55:01', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:55:03', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'None (0)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:55:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered 'No (N)'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-05T19:55:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '1010630f-c2ce-41cc-ba41-b765eff26a8d'	System	06 Sep 2020 00:55:10
User entered '05 Sep 2020 19:55'	System	06 Sep 2020 00:55:10

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	31 Aug 2020 15:26:30
User entered 'Day 7'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:14', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:15', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:19', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'None (0)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered 'No (N)'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-09-06T18:46:25', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '70521b84-b181-449d-ba0f-294821ef1f03'	System	06 Sep 2020 23:46:27
User entered '06 Sep 2020 18:46'	System	06 Sep 2020 23:46:27

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:26:30

US3212004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:26:30

US3212004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:52:22

US3212004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '07 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:45:44
User entered '7 Sep 2020'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:52:22

US3212004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:52:22

US3212004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:52:22

US3212004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:52:27

US3212004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	08 Sep 2020 14:52:27

US3212004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Sep 2020 13:57:37

US3212004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '14 Sep 2020'	Laura Ngansop Djampou (b) (4)	15 Sep 2020 13:57:37

US3212004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	15 Sep 2020 13:57:37

US3212004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	15 Sep 2020 13:57:37

US3212004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Sep 2020 13:57:44

US3212004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	15 Sep 2020 13:57:44

US3212004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:32:04

US3212004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '21 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:34:53
User entered '22 Sep 2020'	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:32:04

US3212004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:32:04

US3212004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:32:04

US3212004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	22 Sep 2020 16:32:15

US3212004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	22 Sep 2020 16:32:15

US3212004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Sep 2020 15:08:12

US3212004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '28 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 15:08:12

US3212004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	28 Sep 2020 15:08:12

US3212004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'VISIT3'	System	28 Sep 2020 15:08:12

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '28 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '09:12' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:45:55
User entered '9:12'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '28 Sep 2020 09:12'	System	11 Dec 2020 14:45:55
User entered '28 Sep 2020 9:12'	System	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '97.3' F	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered empty.	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '71'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'bpm'	System	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '16'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'breaths/min'	System	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '134'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '80'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'mmHg'	System	28 Sep 2020 15:09:16

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17

US3212004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17

US3212004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:47

US3212004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '28 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:47

US3212004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:59

US3212004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '28 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:59

US3212004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '09:53' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Dec 2020 14:46:05
User entered '9:53'	Afifah Ayub (b) (4)	28 Sep 2020 15:09:59

US3212004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '28 Sep 2020 09:53'	System	11 Dec 2020 14:46:05
User entered '28 Sep 2020 9:53'	System	28 Sep 2020 15:09:59

US3212004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Sep 2020 15:10:02

US3212004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered '1'	System	28 Sep 2020 15:10:02

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 64'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-03T08:06:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6767aaa4-48a5-48ca-b5e0-17bccb1748a4'	System	03 Oct 2020 13:07:02
User entered 'No (N)'	System	03 Oct 2020 13:07:02

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-03T08:06:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6767aaa4-48a5-48ca-b5e0-17bccb1748a4'	System	03 Oct 2020 13:07:02
User entered 'No (N)'	System	03 Oct 2020 13:07:02

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-03T08:06:59', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6767aaa4-48a5-48ca-b5e0-17bccb1748a4'	System	03 Oct 2020 13:07:02
User entered '03 Oct 2020 08:06:59'	System	03 Oct 2020 13:07:02

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 71'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-10T11:17:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95025f2c-0522-4b1a-81af-be05e33a1624'	System	10 Oct 2020 16:17:39
User entered 'No (N)'	System	10 Oct 2020 16:17:39

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-10T11:17:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95025f2c-0522-4b1a-81af-be05e33a1624'	System	10 Oct 2020 16:17:39
User entered 'No (N)'	System	10 Oct 2020 16:17:39

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-10T11:17:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '95025f2c-0522-4b1a-81af-be05e33a1624' User entered '10 Oct 2020 11:17:37'	System	10 Oct 2020 16:17:39
	System	10 Oct 2020 16:17:39

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 78'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-17T01:49:07', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '0486724d-d662-49ad-a6ed-e3ef0d09170d'	System	17 Oct 2020 06:49:15
User entered 'No (N)'	System	17 Oct 2020 06:49:15

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-17T01:49:10', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '0486724d-d662-49ad-a6ed-e3ef0d09170d'	System	17 Oct 2020 06:49:15
User entered 'No (N)'	System	17 Oct 2020 06:49:15

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-17T01:49:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '0486724d-d662-49ad-a6ed-e3ef0d09170d' User entered '17 Oct 2020 01:49:13'	System	17 Oct 2020 06:49:15
	System	17 Oct 2020 06:49:15

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 92'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-31T09:48:25', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '48cc0243-4f4c-4286-a90b-8d4e1ca57dca'	System	31 Oct 2020 14:48:42
User entered 'No (N)'	System	31 Oct 2020 14:48:42

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-31T09:48:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '48cc0243-4f4c-4286-a90b-8d4e1ca57dca'	System	31 Oct 2020 14:48:42
User entered 'No (N)'	System	31 Oct 2020 14:48:42

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-10-31T09:48:37', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '48cc0243-4f4c-4286-a90b-8d4e1ca57dca'	System	31 Oct 2020 14:48:42
User entered '31 Oct 2020 09:48:37'	System	31 Oct 2020 14:48:42

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 99'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-07T07:20:21', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5aac34ff-f8b9-45d0-8254-f4eaffc6460f'	System	07 Nov 2020 13:20:33
User entered 'No (N)'	System	07 Nov 2020 13:20:33

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-07T07:20:24', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5aac34ff-f8b9-45d0-8254-f4eaffc6460f'	System	07 Nov 2020 13:20:33
User entered 'No (N)'	System	07 Nov 2020 13:20:33

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-07T07:20:26', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5aac34ff-f8b9-45d0-8254-f4eaffc6460f' User entered '07 Nov 2020 07:20:26'	System	07 Nov 2020 13:20:33
	System	07 Nov 2020 13:20:33

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered 'Day 106'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-14T01:19:39', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '01133bca-17aa-4347-8751-502f6fb4643a'	System	14 Nov 2020 07:19:49
User entered 'No (N)'	System	14 Nov 2020 07:19:49

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-14T01:19:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '01133bca-17aa-4347-8751-502f6fb4643a'	System	14 Nov 2020 07:19:49
User entered 'No (N)'	System	14 Nov 2020 07:19:49

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-14T01:19:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '01133bca-17aa-4347-8751-502f6fb4643a' User entered '14 Nov 2020 01:19:47'	System	14 Nov 2020 07:19:49
	System	14 Nov 2020 07:19:49

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 16:43:29

US3212004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:01:33
Data entry locked.	System	03 Aug 2020 16:43:29
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 16:43:29

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-11-20T18:36:41', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ccb40dcd-fa64-41c9-b67c-12c32a15cda8'	System	21 Nov 2020 00:38:54
User entered 'No (N)'	System	21 Nov 2020 00:38:54

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-11-20T18:36:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ccb40dcd-fa64-41c9-b67c-12c32a15cda8'	System	21 Nov 2020 00:38:54
User entered 'No (N)'	System	21 Nov 2020 00:38:54

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-20T18:36:46', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'ccb40dcd-fa64-41c9-b67c-12c32a15cda8' User entered '20 Nov 2020 18:36:46'	System	21 Nov 2020 00:38:54

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-11-25T07:23:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4b0c7bad-5ae8-4e93-8918-8488812f53e3'	System	25 Nov 2020 13:23:47
User entered 'No (N)'	System	25 Nov 2020 13:23:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-11-25T07:23:42', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4b0c7bad-5ae8-4e93-8918-8488812f53e3'	System	25 Nov 2020 13:23:47
User entered 'No (N)'	System	25 Nov 2020 13:23:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-11-25T07:23:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '4b0c7bad-5ae8-4e93-8918-8488812f53e3' User entered '25 Nov 2020 07:23:45'	System	25 Nov 2020 13:23:47
	System	25 Nov 2020 13:23:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-02T08:04:04', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered 'Yes (Y)'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-12-02T08:04:08', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered 'No (N)'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-02T08:04:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered 'Yes (Y)'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '1'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '1'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb' User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb' User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb' User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb' User entered '1'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '1'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:04:40', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered '0'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Please 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 (d688120233d98b02)', Time: '2020-12-02T08:05:05', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-02T08:05:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb'	System	02 Dec 2020 14:05:23
User entered 'No (N)'	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-02T08:05:13', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '124eede9-a80a-48b9-aa10-e90fa9067fcb' User entered '02 Dec 2020 08:05:13'	System	02 Dec 2020 14:05:23
	System	02 Dec 2020 14:05:23

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-09T03:45:35', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'Yes (Y)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-12-09T03:45:43', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'Yes (Y)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Please 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 (d688120233d98b02)', Time: '2020-12-09T03:45:48', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-09T03:45:53', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'Yes (Y)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '1'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '1'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '1'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '1'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '1'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:09', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '0'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Please 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 (d688120233d98b02)', Time: '2020-12-09T03:46:11', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-09T03:46:16', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'Yes (Y)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Please 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 (d688120233d98b02)', Time: '2020-12-09T03:46:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-09T03:46:21', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'a23f395a-904d-4e5f-82be-c7265e2d6805'	System	09 Dec 2020 09:46:31
User entered '09 Dec 2020 03:46:21'	System	09 Dec 2020 09:46:31

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-16T05:16:30', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9150e2bd-d357-4602-bc3d-512be1a8b505'	System	16 Dec 2020 11:16:37
User entered 'No (N)'	System	16 Dec 2020 11:16:37

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-12-16T05:16:31', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9150e2bd-d357-4602-bc3d-512be1a8b505'	System	16 Dec 2020 11:16:37
User entered 'No (N)'	System	16 Dec 2020 11:16:37

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-16T05:16:34', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9150e2bd-d357-4602-bc3d-512be1a8b505' User entered '16 Dec 2020 05:16:34'	System	16 Dec 2020 11:16:37
	System	16 Dec 2020 11:16:37

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-26T20:50:49', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '61a339eb-c09b-4c34-b366-8777396b061b'	System	27 Dec 2020 02:51:06
User entered 'No (N)'	System	27 Dec 2020 02:51:06

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-12-26T20:50:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '61a339eb-c09b-4c34-b366-8777396b061b'	System	27 Dec 2020 02:51:06
User entered 'No (N)'	System	27 Dec 2020 02:51:06

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-26T20:51:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '61a339eb-c09b-4c34-b366-8777396b061b' User entered '26 Dec 2020 20:51:00'	System	27 Dec 2020 02:51:06

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2020-12-30T00:01:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '69d7b663-6220-4a3e-915a-fdc08bb22192'	System	30 Dec 2020 06:02:05
User entered 'No (N)'	System	30 Dec 2020 06:02:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2020-12-30T00:01:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '69d7b663-6220-4a3e-915a-fdc08bb22192'	System	30 Dec 2020 06:02:05
User entered 'No (N)'	System	30 Dec 2020 06:02:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2020-12-30T00:02:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '69d7b663-6220-4a3e-915a-fdc08bb22192'	System	30 Dec 2020 06:02:05
User entered '30 Dec 2020 00:02:00'	System	30 Dec 2020 06:02:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-01-06T08:18:42', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd7ab5375-c5a1-4fa4-9740-6c83928e985e'	System	06 Jan 2021 14:18:50
User entered 'No (N)'	System	06 Jan 2021 14:18:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-01-06T08:18:45', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd7ab5375-c5a1-4fa4-9740-6c83928e985e'	System	06 Jan 2021 14:18:50
User entered 'No (N)'	System	06 Jan 2021 14:18:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-01-06T08:18:47', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd7ab5375-c5a1-4fa4-9740-6c83928e985e' User entered '06 Jan 2021 08:18:47'	System	06 Jan 2021 14:18:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-01-13T00:33:36', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9c74ee86-b1bd-4617-806c-2dc6ddcf8946'	System	13 Jan 2021 06:33:47
User entered 'No (N)'	System	13 Jan 2021 06:33:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-01-13T00:33:42', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9c74ee86-b1bd-4617-806c-2dc6ddcf8946'	System	13 Jan 2021 06:33:47
User entered 'No (N)'	System	13 Jan 2021 06:33:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-01-13T00:33:44', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '9c74ee86-b1bd-4617-806c-2dc6ddcf8946'	System	13 Jan 2021 06:33:47
User entered '13 Jan 2021 00:33:44'	System	13 Jan 2021 06:33:47

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-01-20T08:53:18', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5c270381-8127-4915-962c-75ad62d23a88'	System	20 Jan 2021 14:53:28
User entered 'No (N)'	System	20 Jan 2021 14:53:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-01-20T08:53:20', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5c270381-8127-4915-962c-75ad62d23a88'	System	20 Jan 2021 14:53:28
User entered 'No (N)'	System	20 Jan 2021 14:53:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-01-20T08:53:22', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '5c270381-8127-4915-962c-75ad62d23a88'	System	20 Jan 2021 14:53:28
User entered '20 Jan 2021 08:53:22'	System	20 Jan 2021 14:53:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-01-27T07:36:54', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd662883f-850a-4dfc-a5f6-f55975b3ca18'	System	27 Jan 2021 13:37:05
User entered 'No (N)'	System	27 Jan 2021 13:37:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-01-27T07:36:57', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd662883f-850a-4dfc-a5f6-f55975b3ca18'	System	27 Jan 2021 13:37:05
User entered 'No (N)'	System	27 Jan 2021 13:37:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-01-27T07:37:02', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'd662883f-850a-4dfc-a5f6-f55975b3ca18'	System	27 Jan 2021 13:37:05
User entered '27 Jan 2021 07:37:02'	System	27 Jan 2021 13:37:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-02-03T08:00:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7b83afe8-5079-4bca-b1b1-2b95bf6b7318'	System	03 Feb 2021 14:00:11
User entered 'No (N)'	System	03 Feb 2021 14:00:11

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-02-03T08:00:04', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7b83afe8-5079-4bca-b1b1-2b95bf6b7318'	System	03 Feb 2021 14:00:11
User entered 'No (N)'	System	03 Feb 2021 14:00:11

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-02-03T08:00:06', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '7b83afe8-5079-4bca-b1b1-2b95bf6b7318'	System	03 Feb 2021 14:00:11
User entered '03 Feb 2021 08:00:06'	System	03 Feb 2021 14:00:11

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-02-10T06:42:52', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e7cda4b4-2a27-4937-a676-4a4133af480c'	System	10 Feb 2021 12:43:05
User entered 'No (N)'	System	10 Feb 2021 12:43:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-02-10T06:42:58', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e7cda4b4-2a27-4937-a676-4a4133af480c'	System	10 Feb 2021 12:43:05
User entered 'No (N)'	System	10 Feb 2021 12:43:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-02-10T06:43:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'e7cda4b4-2a27-4937-a676-4a4133af480c' User entered '10 Feb 2021 06:43:00'	System	10 Feb 2021 12:43:05

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-02-24T07:53:34-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6f236b2b-b930-40e2-a8a3-51fbcc17d7ad'	System	24 Feb 2021 13:53:44
User entered 'No (N)'	System	24 Feb 2021 13:53:44

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-02-24T07:53:40-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6f236b2b-b930-40e2-a8a3-51fbcc17d7ad'	System	24 Feb 2021 13:53:44
User entered 'No (N)'	System	24 Feb 2021 13:53:44

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-02-24T07:53:42-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '6f236b2b-b930-40e2-a8a3-51fbcc17d7ad' User entered '24 Feb 2021 07:53:42'	System	24 Feb 2021 13:53:44
	System	24 Feb 2021 13:53:44

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-03T15:46:24-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered 'Yes (Y)'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-03-03T15:46:32-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc'	System	03 Mar 2021 21:47:38
User entered 'No (N)'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-03T15:46:49-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered 'Yes (Y)'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '1'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '1'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '1'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:07-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '0'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Please 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 (d688120233d98b02)', Time: '2021-03-03T15:47:13-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc'	System	03 Mar 2021 21:47:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-03T15:47:20-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc'	System	03 Mar 2021 21:47:38
User entered 'No (N)'	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-03T15:47:27-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '32c023a4-0dc1-4d0d-827c-2d14133d08fc' User entered '03 Mar 2021 15:47:27'	System	03 Mar 2021 21:47:38
	System	03 Mar 2021 21:47:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-10T00:19:12-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15e5a545-aa0f-4a41-8559-64960d5e1053'	System	10 Mar 2021 06:19:22
User entered 'No (N)'	System	10 Mar 2021 06:19:22

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-03-10T00:19:18-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15e5a545-aa0f-4a41-8559-64960d5e1053'	System	10 Mar 2021 06:19:22
User entered 'No (N)'	System	10 Mar 2021 06:19:22

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-10T00:19:20-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '15e5a545-aa0f-4a41-8559-64960d5e1053'	System	10 Mar 2021 06:19:22
User entered '10 Mar 2021 00:19:20'	System	10 Mar 2021 06:19:22

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-17T00:01:29-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'bc15bd17-1095-424e-b5e2-75a2dcf85c33'	System	17 Mar 2021 05:01:50
User entered 'No (N)'	System	17 Mar 2021 05:01:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-03-17T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'bc15bd17-1095-424e-b5e2-75a2dcf85c33'	System	17 Mar 2021 05:01:50
User entered 'No (N)'	System	17 Mar 2021 05:01:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-17T00:01:45-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'bc15bd17-1095-424e-b5e2-75a2dcf85c33'	System	17 Mar 2021 05:01:50
User entered '17 Mar 2021 00:01:45'	System	17 Mar 2021 05:01:50

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-03-24T06:50:20-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f18a92be-1c32-47a3-a41a-bb5100e9d8cb' User entered 'No (N)'	System	24 Mar 2021 11:50:28
	System	24 Mar 2021 11:50:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-03-24T06:50:22-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f18a92be-1c32-47a3-a41a-bb5100e9d8cb'	System	24 Mar 2021 11:50:28
User entered 'No (N)'	System	24 Mar 2021 11:50:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-24T06:50:25-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'f18a92be-1c32-47a3-a41a-bb5100e9d8cb' User entered '24 Mar 2021 06:50:25'	System	24 Mar 2021 11:50:28
	System	24 Mar 2021 11:50:28

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-04-07T14:44:36-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '37478421-0570-4763-898c-96a1ab6e5c94'	System	07 Apr 2021 19:44:51
User entered 'No (N)'	System	07 Apr 2021 19:44:51

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-04-07T14:44:38-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '37478421-0570-4763-898c-96a1ab6e5c94'	System	07 Apr 2021 19:44:51
User entered 'No (N)'	System	07 Apr 2021 19:44:51

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-04-07T14:44:42-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '37478421-0570-4763-898c-96a1ab6e5c94'	System	07 Apr 2021 19:44:51
User entered '07 Apr 2021 14:44:42'	System	07 Apr 2021 19:44:51

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[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 (d688120233d98b02)', Time: '2021-04-28T00:01:27-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c7f90a81-6c97-463b-b20d-8221da6cff81'	System	28 Apr 2021 05:01:38
User entered 'No (N)'	System	28 Apr 2021 05:01:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

Have you been exposed to someone with 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 (d688120233d98b02)', Time: '2021-04-28T00:01:31-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c7f90a81-6c97-463b-b20d-8221da6cff81'	System	28 Apr 2021 05:01:38
User entered 'No (N)'	System	28 Apr 2021 05:01:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-04-28T00:01:33-05:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: 'c7f90a81-6c97-463b-b20d-8221da6cff81'	System	28 Apr 2021 05:01:38
User entered '28 Apr 2021 00:01:33'	System	28 Apr 2021 05:01:38

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:47:27

US3212004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:47:27
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:47:27

US3212004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:42:51

[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 07:27:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-02T18:26:46-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52f91671-c4f8-4ade-a3cb-2049624e9f68'	System	03 Mar 2021 00:26:55
User entered 'No (N)'	System	03 Mar 2021 00:26:55

US3212004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:42:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:27:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d688120233d98b02)', Time: '2021-03-02T18:26:51-06:00', User OID: 'PatientReportedOutcome (US3212004)', ODM File OID: '52f91671-c4f8-4ade-a3cb-2049624e9f68'	System	03 Mar 2021 00:26:55
User entered '02 Mar 2021 18:26:51'	System	03 Mar 2021 00:26:55

US3212004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:02:26

US3212004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '23 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:02:26

US3212004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:02:26

US3212004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:02:26

US3212004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:02:31

US3212004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:17
User entered 'I'	System	26 Oct 2020 17:02:31

US3212004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:01:51
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Dec 2020 14:36:08

US3212004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:01:51
User entered '30 Nov 2020'	Laura Ngansop Djampou (b) (4)	01 Dec 2020 14:36:08

US3212004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:01:51
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Dec 2020 14:36:08

US3212004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Dec 2020 14:36:08

US3212004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:01:55
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Dec 2020 14:35:57

US3212004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'I'	System	01 Dec 2020 14:35:57

US3212004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:47:49
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:46:20
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:13:14

US3212004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:47:51
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:46:20
User entered '29 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Jan 2021 21:54:14
User entered '28 Dec 2020'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:13:14

US3212004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:47:53
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:46:20
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Jan 2021 21:54:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:13:14

US3212004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:47:54
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:46:20
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Jan 2021 21:54:14
User entered 'Called for day 149, no answer, left a voicemail'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:13:14

US3212004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 18:47:59
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:46:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:13:06

US3212004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'I'	System	29 Dec 2020 17:13:06

US3212004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Jan 2021 15:46:28

US3212004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '27 Jan 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:47:11
User entered '26 Jan 2021'	Laura Ngansop Djampou (b) (4)	27 Jan 2021 15:46:28

US3212004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:47:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	27 Jan 2021 15:46:28

US3212004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Feb 2021 19:47:11
User entered 'Called for day 179, no answer, left voicemail'	Laura Ngansop Djampou (b) (4)	27 Jan 2021 15:46:28

US3212004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Jan 2021 15:46:35

US3212004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'I'	System	27 Jan 2021 15:46:35

US3212004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:05

US3212004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:05

US3212004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[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 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:05

US3212004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'VISIT4'	System	03 Mar 2021 17:51:05

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '12:44'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered '02 Mar 2021 12:44'	System	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '98.1' F	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '76'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'bpm'	System	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '16'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'breaths/min'	System	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '134'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'mmHg'	System	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '90'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'mmHg'	System	30 Mar 2021 18:13:18

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19

US3212004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19

US3212004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:17

US3212004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:17

US3212004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:31

US3212004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:31

US3212004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered '13:40'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:31

US3212004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered '02 Mar 2021 13:40'	System	03 Mar 2021 17:51:31

US3212004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:51:35

US3212004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:57:19
User entered 'I'	System	03 Mar 2021 17:51:35

US3212004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:00:59
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Mar 2021 14:26:24

US3212004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:00:59
User entered '26 Mar 2021'	Laura Ngansop Djampou (b) (4)	29 Mar 2021 14:26:24

US3212004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:00:59
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	29 Mar 2021 14:26:24

US3212004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:00:59
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Mar 2021 14:26:24

US3212004

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:00:59
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Mar 2021 14:26:40

US3212004

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'I'	System	29 Mar 2021 14:26:40

US3212004

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Apr 2021 13:39:56

US3212004

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '26 Apr 2021'	Laura Ngansop Djampou (b) (4)	27 Apr 2021 13:39:56

US3212004

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	27 Apr 2021 13:39:56

US3212004

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Apr 2021 13:39:56

US3212004

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Apr 2021 13:40:04

US3212004

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 13:40:04

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:03
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:50:45
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 17:56:53

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:03
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:50:45
User entered '10:19'	Afifah Ayub (b) (4)	02 Dec 2020 17:56:53

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:03
User entered '02 Dec 2020 10:19'	System	02 Dec 2020 17:56:53

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:03
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:50:45
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Afifah Ayub (b) (4)	02 Dec 2020 17:56:53

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:03
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:50:45
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 17:56:53

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 1 (Day 1)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:05
User entered '01 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:10
User entered '0'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:12
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User entered '%'	System	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:14
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:16
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:19
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:25
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:26
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:30
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:36
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:40
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:47
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:48
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:49
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:55
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:00:58
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:01:03
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:01:08
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:01:10
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:01:00
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 17:59:43

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:26
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:45
User entered '0'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:44
User entered '98'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User entered '%'	System	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:35
User entered '98.2' F	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:53
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:04:58
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:15
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:19
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:22
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:25
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:29
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:31
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:40
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:37
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:49
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:52
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:58
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:06:02
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:06:04
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 23:05:46
User entered 'None (None)'	Afifah Ayub (b) (4)	02 Dec 2020 18:01:50

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:48:08
User entered '03 Dec 2020'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:48:09
User entered '0'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:41:55
User entered '100'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User entered '%'	System	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:41:57
User entered '98.3' F	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:48:59
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:21
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:24
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:28
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:32
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:36
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:43
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:46
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:49
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:51
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:03
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:07
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:12
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:17
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:19
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:49:59
User entered 'None (None)'	Afifah Ayub (b) (4)	04 Dec 2020 16:50:32

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:46
User entered '04 Dec 2020'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:48
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:58
User entered '100'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User entered '%'	System	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:56
User entered '98.3' F	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:12
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:15
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:17
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:19
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:24
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:29
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:34
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:36
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:43
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:40
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:01
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:03
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:09
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:11
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:14
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:51:50
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:10:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:31
User entered '05 Dec 2020'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:34
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:38
User entered '100'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User entered '%'	System	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:39
User entered '99.4' F	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:48
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:53
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:57
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:52:59
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:03
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:07
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:22
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:24
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:28
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:30
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:41
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:44
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:47
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:49
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:52
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 15:53:36
User entered 'None (None)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:40

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[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 03:24:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[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 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:38:49
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
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)	09 Apr 2021 07:45:25
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 'Please see AE 4 in AEs' (Site from System).	Heather Leary (b) (4)	08 Apr 2021 14:59:17
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	08 Apr 2021 13:36:28
DataPoint Un-verified.	Afifah Ayub (b) (4)	08 Apr 2021 13:36:28
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:36:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:36:28
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 17:34:07
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Dec 2020 15:11:46
Query 'Data is required. Please complete.' answered with 'adding later' (Site from System).	Afifah Ayub (b) (4)	02 Dec 2020 18:02:13
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 18:02:08
User entered empty.	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:39:01
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4)	15 Apr 2021 14:54:14
DataPoint Un-verified.	Afifah Ayub (b) (4)	09 Apr 2021 18:08:37
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 18:08:37
User entered '07 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 18:08:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:41:12
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is recorded under Illness Visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is recorded under Illness Visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'updated; saliva sample from 04DEC2020 is the correct sample' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 06:06:16
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is recorded under Illness Visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	Heather Leary (b) (4) (b) (4)	15 Apr 2021 14:55:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is recorded under Illness Visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 07:01:23
Signature has been broken.	Afifah Ayub (b) (4) (b) (4)	09 Apr 2021 18:08:37
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	09 Apr 2021 18:08:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

1962 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Afifah Ayub Swab)'	(b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered empty.	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[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 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:17:24
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:21
DataPoint Un-verified.	Heather Leary (b) (4)	19 Apr 2021 17:08:43
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 17:08:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:55:02
User closed query 'Please update response to reflect study lab results per date and test type.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:54:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:53:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:53:42
Query 'Please update response to reflect study lab results per date and test type.' answered with 'updated' (Site from CRA).	Jagruti Patel (b) (4)	19 Apr 2021 14:35:40
Signature has been broken.	Jagruti Patel (b) (4)	19 Apr 2021 14:34:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	19 Apr 2021 14:34:54
User opened query 'Please update response to reflect study lab results per date and test type.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 10:49:29
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 10:48:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered 'No (N)'	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:17:28
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:21
User closed query 'Data is only applicable for the sample collected at hospital. The sample form 04Dec20 was completed by subject in home setting. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:48:20
Query 'Data is only applicable for the sample collected at hospital. The sample form 04Dec20 was completed by subject in home setting. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4) (b) (4)	19 Apr 2021 17:09:02
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:08:43
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:08:22
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 17:08:22
User opened query 'Data is only applicable for the sample collected at hospital. The sample form 04Dec20 was completed by subject in home setting. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:02:10
User closed query 'Please remove data from this bottom section of page.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:02:10
Query 'Please remove data from this bottom section of page.' answered with 'Data is required per earlier query' (Site from CRA).	Heather Leary (b) (4) (b) (4)	19 Apr 2021 16:00:04
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:59:46
User entered 'HCA TOMBALL' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:59:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:58:14
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:58:14
User opened query 'Please remove data from this bottom section of page.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:55:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

1966 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 14:35:35
Signature has been broken.	Jagruti Patel (b) (4) (b) (4)	19 Apr 2021 14:35:35
User entered 'HCA Tomball' reason for change: Data Entry Error	Jagruti Patel (b) (4) (b) (4)	19 Apr 2021 14:35:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 14:34:54
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 10:48:36
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered empty.	Afifah Ayub (b) (4) (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:17:31
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:21
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:08:43
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:08:22
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 17:08:22
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:59:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 15:59:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 15:58:30
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 15:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 14:35:35
Signature has been broken.	Jagruti Patel (b) (4)	19 Apr 2021 14:35:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	19 Apr 2021 14:35:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 14:34:54
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:53:47
User entered empty.	Afifah Ayub (b) (4)	02 Dec 2020 18:02:08

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:31
User entered '1'	System	08 Apr 2021 13:36:28
User entered '0'	System	07 Dec 2020 15:11:46

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[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 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4) (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[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 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:42
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 01:18:47
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
User entered empty.	Afifah Ayub (b) (4)	08 Apr 2021 13:38:13

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:42:51

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:24:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:38:04
User entered 'No (N)'	Afifah Ayub (b) (4)	02 Dec 2020 18:02:23

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:12:53
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 11:12:53
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 06:35:47
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:35:47
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	09 Apr 2021 06:35:47
User entered '02 Dec 2021' reason for change: Data Entry Error	System	09 Apr 2021 06:35:42
User entered '02 Dec 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:35:42
DataPoint activated with code reason code Data required.	(b) (4)	09 Apr 2021 06:35:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:18:57
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 15:00:21
User opened query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:38:56
User entered empty; reason for change Data Entry Error	(b) (4)	08 Apr 2021 13:38:56
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:38:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:38:35
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 13:38:35
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:34:20
Signature has been broken.	System	08 Apr 2021 13:34:20
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:34:20
User signature succeeded.	(b) (4)	08 Apr 2021 13:34:20
User closed query 'Future date has been entered. Please correct.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 13:32:46
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	08 Apr 2021 13:32:46
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 13:32:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	26 Mar 2021 17:21:18
User entered '02 Dec 2020' reason for change: Data Entry Error	System	24 Mar 2021 15:13:29
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	24 Mar 2021 15:13:29
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 15:13:29

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	24 Mar 2021 15:13:25
User entered '02 Dec 2021'	Afifah Ayub (b) (4) (b) (4)	24 Mar 2021 15:13:25

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered '10:19' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 11:12:56
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	09 Apr 2021 06:35:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 15:18:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 15:00:21
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:38:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 13:38:35
User entered '10:19' reason for change: Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:38:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 13:34:20
User entered '10:19' reason for change: Data Entry Error	System	08 Apr 2021 13:34:20
User opened query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:34:20
Signature has been broken.	(b) (4)	
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
User signature succeeded.	(b) (4)	
User entered '10:19'	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	Afifah Ayub (b) (4)	24 Mar 2021 15:13:25
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Dec 2020 10:19'	System	09 Apr 2021 06:35:47
User entered '02 Dec 2021 10:19'	System	09 Apr 2021 06:35:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:21
User entered empty.	System	08 Apr 2021 13:38:35
User entered '02 Dec 2020 10:19'	System	08 Apr 2021 13:34:20
User entered empty.	System	08 Apr 2021 13:32:46
User entered '02 Dec 2020 10:19'	System	24 Mar 2021 15:13:29
User entered '02 Dec 2021 10:19'	System	24 Mar 2021 15:13:25

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:12:58
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:35:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:21
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:00
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:38:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:38:35
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:34:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 13:34:20
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:34:20
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:32:46
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:25

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
User signature succeeded.	Insia Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 06:35:42
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	08 Apr 2021 15:18:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Apr 2021 15:00:21
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 13:39:02
User opened query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:38:35
User entered empty; reason for change Data Entry Error	System	08 Apr 2021 13:38:35
User closed query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:34:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	08 Apr 2021 13:34:20
User entered 'Yes (Y)' reason for change: Data Entry Error	System	08 Apr 2021 13:32:46
User opened query 'Data is required. Please complete.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:32:46
Signature has been broken.	(b) (4)	08 Apr 2021 13:32:46
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	26 Mar 2021 17:21:18
User signature succeeded.	(b) (4)	24 Mar 2021 15:13:25
User entered 'Yes (Y)'	Vicki Miller (b) (4)	
	(b) (4)	
	Afifah Ayub (b) (4)	
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:10
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 06:36:30
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:30
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 06:36:23
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User entered '02 Dec 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:39:35
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:12
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:39:35
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:15
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:39:35
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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)	26 Mar 2021 08:36:27
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 'updating' (Site from System).	Afifah Ayub (b) (4)	24 Mar 2021 15:14:57
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	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is recorded under Participant Decision Visit / OL-D1 in EDC and was performed in central lab, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4)	12 Apr 2021 11:11:05
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 18:08:52
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 17:57:56
User entered '07 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 17:57:56
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 11:13:29
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 06:36:30
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:30
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 06:36:23
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User entered '02 Dec 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:51

PRODUCTION RELEASE (v12.003
EAB) (1725)

2032 of 3188

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is recorded under Participant Decision Visit / OL-D1 in EDC and was performed in central lab, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the details in the response. Thank you. ' answered with 'subject was not seen on 07Dec2020 at all. subject was seen on 02Dec2020 for COVID illness visit and subject was seen on 02Mar2020 for OL-D1/ participant decision visit. The date is update here correctly from 07Dec2020 to 02Dec2020' (Site from DM).	Jagruti Patel (b) (4)	07 Apr 2021 21:07:59
Signature has been broken.	Jagruti Patel (b) (4)	07 Apr 2021 21:05:43
User entered '02 Dec 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	07 Apr 2021 21:05:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07-DEC-2020 is recorded under Participant Decision Visit / OL-D1 in EDC and was performed in central lab, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date for tracking or else, please ship the sample and provide the details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:08:48
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '07 Dec 2020'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

Type of Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:32
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 06:36:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	(b) (4)	09 Apr 2021 06:36:23
	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
	(b) (4)	09 Apr 2021 06:36:23
	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 13:39:48
Signature has been broken.	System	08 Apr 2021 13:39:35
	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
	(b) (4)	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User signature succeeded.	(b) (4)	08 Apr 2021 13:39:35
	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59
	(b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:14:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 11:13:35
Signature has been broken.	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	09 Apr 2021 06:36:23
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Query 'Data is required. Please complete.' answered with 'Added in error. Please remove folder. Thank you.' (Site from System).	Afifah Ayub (b) (4)	08 Apr 2021 13:39:46
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:39:35
Signature has been broken.	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	08 Apr 2021 13:39:35
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:37
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 06:36:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 15:18:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 15:00:36
User entered '1'	System	24 Mar 2021 15:13:59

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 is recorded under Covid-19 Assessment in EDC, however the same is missing in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:46:17
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:29:29
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 is recorded under Covid-19 Assessment in EDC, however the same is missing in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'please check lab portal' (Site from DM).	Reagan Reed (b) (4)	23 Dec 2020 14:10:52
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 is recorded under Covid-19 Assessment in EDC, however the same is missing in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 12:14:50
User entered '11 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:38:32

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:29:33
User entered '11:49'	Afifah Ayub (b) (4)	14 Dec 2020 14:38:32

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:29
User entered '11 Dec 2020 11:49'	System	14 Dec 2020 14:38:32

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:29:34
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Afifah Ayub (b) (4)	14 Dec 2020 14:38:32

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:51

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:29:38
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Dec 2020 14:38:32

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Please remove the first 5 log lines as they are captured in the first symptom log.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:47:02
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
Query 'Please remove the first 5 log lines as they are captured in the first symptom log.' answered with 'done' (Site from CRA).	Afifah Ayub (b) (4)	23 Dec 2020 17:25:51
User opened query 'Please remove the first 5 log lines as they are captured in the first symptom log.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:38:41
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:21
User entered '06 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:19
User entered 'I'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:17
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:16
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:14
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:13
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:11
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:10
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:07
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:06
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:04
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:03
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:01
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:59
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:57
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:55
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:53
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:50
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:49
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:38:47
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 7 (Day 7)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:25
User entered '07 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:27
User entered 'I'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:28
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:30
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:31
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:33
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:35
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:36
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:38
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:39
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:41
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:44
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:45
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:47
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:49
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:50
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:52
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:53
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:55
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:39:57
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 8 (Day 8)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:15
User entered '08 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:17
User entered 'I'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:19
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:20
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:22
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:23
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:25
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:43
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:45
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:46
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:51
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:54
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:56
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:57
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:43:58
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:44:00
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:44:01
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:44:03
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:44:04
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:44:06
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 9 (Day 9)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:40
User entered '09 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:46
User entered 'I'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:48
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:50
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:52
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:54
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:56
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:57
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:45:59
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:01
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:03
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:04
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:06
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:07
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:09
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:22
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:24
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:26
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:27
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:29
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 10 (Day 10)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:33
User entered '10 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:35
User entered 'I'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:37
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:39
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:40
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:42
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:44
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:46
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:48
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:49
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:50
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:52
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:53
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:55
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:57
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:59
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:00
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:02
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:04
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:06
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 11 (Day 11)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:18
User entered '11 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:20
User entered '0'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:44
User entered '100' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:55:45
	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	14 Dec 2020 14:55:45
User entered empty.	System	14 Dec 2020 14:43:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:46
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:55:45
	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:55:12
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:55:21
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:55:43
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:56:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Dec 2020 12:26:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:22
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:25
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:34
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:37
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:47
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:41
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:53
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:56
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:59
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:58:02
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:58:05
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:57:45
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:43:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 12 (Day 12)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:58:18
User entered '12 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:10
User entered '0'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:13
User entered '100'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	14 Dec 2020 14:44:50

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:15
User entered '98.4' F	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:22
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:26
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:59:32
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:41:22
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Dec 2020 12:26:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:00:43
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:00:52
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:00:54
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:00:56
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:00:59
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:01
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:13
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:15
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:18
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:20
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:22
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:04
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:44:50
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 13 (Day 13)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:47
User entered '13 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:01:49
User entered '0'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per source late entry, O2 saturation was 100%. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 15:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:37:25
Query 'Per source late entry, O2 saturation was 100%. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	19 Jan 2021 21:59:20
User entered '100' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 21:59:14
User opened query 'Per source late entry, O2 saturation was 100%. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 21:44:01
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 21:43:11
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:04:38
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	14 Dec 2020 14:49:21

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per source, temperature reported is 98.0 F. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:52:32
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 17:52:29
Query 'Per source, temperature reported is 98.0 F. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	23 Dec 2020 17:26:16
	(b) (4)	
User entered '98.0' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:26:12
	(b) (4)	
User opened query 'Per source, temperature reported is 98.0 F. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 17:04:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:04:47
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:04:51
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:26
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:24
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:22
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:21
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:19
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:16
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:15
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:13
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:12
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:10
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:09
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:07
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:06
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:04
User entered 'None (None)'	Afifah Ayub (b) (4)	14 Dec 2020 14:49:21
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 14 (Day 14)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:05:57
User entered '14 Dec 2020'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:06:00
User entered '0'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:07:52
User entered '100'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	15 Dec 2020 14:35:45

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:07:54
User entered '98.0' F	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:32
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:36
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:47
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:50
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:52
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:56
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:08:58
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:00
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:02
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:04
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:05
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:07
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:09
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:10
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:12
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:09:14
User entered 'None (None)'	Afifah Ayub (b) (4)	15 Dec 2020 14:35:45
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 15 (Day 15)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:08
User entered '15 Dec 2020'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:10
User entered '0'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:12
User entered '100'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	16 Dec 2020 16:47:08

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:06
User entered '97.5' F	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:23
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:27
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:36
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:49
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:50
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:52
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:54
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:57
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:11:59
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:01
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:02
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:04
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:05
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:07
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:09
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:10
User entered 'None (None)'	Afifah Ayub (b) (4)	16 Dec 2020 16:47:08
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 11 (Day 11)' reason for change:	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
Data Entry Error	(b) (4)	
User entered 'Day 16 (Day 16)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:44
User entered '16 Dec 2020'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:46
User entered '0'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:12:56
User entered '100'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	18 Dec 2020 16:14:28

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:13:01
User entered '98.3' F	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:26
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:37
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:39
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:40
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:42
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:43
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:44
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:46
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:47
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:49
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:51
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:53
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:55
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:56
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:14:58
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:00
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:14:28
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
User entered 'Day 17 (Day 17)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:24
User entered '17 Dec 2020'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:25
User entered '0'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:28
User entered '100'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	18 Dec 2020 16:15:36

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:30
User entered '98.7' F	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:48
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:49
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:51
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:53
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:55
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:57
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:15:59
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:01
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:02
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:04
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:05
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:08
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:10
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:12
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:14
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:16:16
User entered 'None (None)'	Afifah Ayub (b) (4)	18 Dec 2020 16:15:36
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Day 13 (Day 13)' reason for change:	Afifah Ayub (b) (4)	23 Dec 2020 17:27:03
Data Entry Error	(b) (4)	
User entered 'Day 18 (Day 18)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:26:58
User entered '18 Dec 2020'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:20
User entered '0'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:22
User entered '100'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User entered '%'	System	21 Dec 2020 14:39:02

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:26
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:24
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:03
User entered '97.7' F	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:28
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:30
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:32
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:33
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:35
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:36
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:38
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:40
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:42
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:43
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:45
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:47
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:49
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:50
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:52
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:42:51

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:22:19
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:27:53
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Dec 2020 14:39:02
	(b) (4)	

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for tracking as the sample is still missing in PPD. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:48:59
Query 'Per GCL Lab Reconciliation requery: Swab: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for tracking as the sample is still missing in PPD. ' answered with 'Accession number: 1F61637 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 18:43:37
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for tracking as the sample is still missing in PPD. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:47:43
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 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 for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:47:43

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 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 for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession number: 1F61637' (Site from DM).	Reagan Reed (b) (4) (b) (4)	20 Jan 2021 22:39:49
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 11DEC2020 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 for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:33:02
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:15
User entered '11 Dec 2020'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:17
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:28
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)	21 Dec 2020 22:14:28
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 'done' (Site from System).	Afifah Ayub (b) (4)	14 Dec 2020 14:51:12
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	14 Dec 2020 14:51:04
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:35:32
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' answered with 'test done at outside facility. no PCR swab to submit to PPD' (Site from DM).	Reagan Reed (b) (4)	29 Jan 2021 17:53:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 07DEC2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 11:56:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:29
User entered '07 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:11:32
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

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)	30 Apr 2021 21:47:52
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
User closed query 'Per Subject reporting the PCR Swab was collected at 'HCA Houston ER Tomball'. Please verify and update this response to yes if applicable and complete the section below.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 21:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:36:14
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
Query 'Per Subject reporting the PCR Swab was collected at 'HCA Houston ER Tomball'. Please verify and update this response to yes if applicable and complete the section below.' answered with 'PCR done at HCA as well as processed one from our site' (Site from CRA).	Reagan Reed (b) (4)	20 Jan 2021 22:40:45
User opened query 'Per Subject reporting the PCR Swab was collected at 'HCA Houston ER Tomball'. Please verify and update this response to yes if applicable and complete the section below.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 20:50:59
Query 'The date of test and type of test listed in response do not match what is entered in the eCRF. Please update information to match what has been collected in source.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 20:10:31
User opened query 'The date of test and type of test listed in response do not match what is entered in the eCRF. Please update information to match what has been collected in source.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:44:25
User closed query 'Per source, test was completed while subject was in the Houston ER. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:44:25

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Query 'Per source, test was completed while subject was in the Houston ER. Please verify and update accordingly.' answered with 'subject received positive salvia from us @ day three illness collected 04DEC and results back to site on 10DEC2020 please advise ' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	29 Dec 2020 15:50:49
User opened query 'Per source, test was completed while subject was in the Houston ER. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:12:47
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:55
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
User entered 'HCA Tomball' reason for change:	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
Data Entry Error	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:57:57
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 19:35:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:42:51

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:52
User entered 'I'	System	14 Dec 2020 14:51:04

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[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)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
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US3212004

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
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User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

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Generated On: 09 Jun 2021 15:42:51

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
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Audit	User	Time (GMT)
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User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

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Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

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Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

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Generated On: 09 Jun 2021 15:42:51

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
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DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:42:51

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered 'No (N)'	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

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Generated On: 09 Jun 2021 15:42:51

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:47:57
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:52:50
User entered empty.	Afifah Ayub (b) (4)	15 Dec 2020 14:34:46

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered '04 Dec 2020'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 15:12:52

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:17
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:52
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:16
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:18
User entered '04 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:54:36
User entered '13 Dec 2020'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:54:36
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:34
User entered '11 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:54:36
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:54:59
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:05:55
User entered '13 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Dec 2020 14:54:59
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:06:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Dec 2020 16:47:22
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:06:17
User entered '15 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Dec 2020 16:47:22
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:06:28
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	22 Dec 2020 14:42:37
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:06:30
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:50:43
	(b) (4), (b) (6)	
User closed query 'Please update once sample has been collected.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 15:39:12
Query 'Please update once sample has been collected.' answered with 'n/a' (Site from CRA).	Heather Leary (b) (4)	19 Jan 2021 20:22:23
User opened query 'Please update once sample has been collected.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 23:07:32
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	22 Dec 2020 14:42:37
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:50:45
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	14 Dec 2020 14:53:21

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:50:51
Query 'Please update once sample has been collected.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 15:50:31
User opened query 'Please update once sample has been collected.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 23:07:50
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	22 Dec 2020 14:42:37
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:50:52
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:53:21
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:55:53
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 18:03:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:55:53
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:03:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:55:53
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	02 Dec 2020 18:03:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	02 Dec 2020 18:03:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '10:20'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Dec 2020 10:20'	System	02 Dec 2020 18:04:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '98.2' F	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered empty.	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '76'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Dec 2020 18:04:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '14'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Dec 2020 18:04:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '112'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Dec 2020 18:04:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:56:16
User entered '70'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:28
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Dec 2020 18:04:28

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:22
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:39
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:22
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:39
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:40
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:49
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:40
User entered '02 Dec 2020'	Afifah Ayub (b) (4)	02 Dec 2020 18:04:49
	(b) (4)	

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:52:32

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:32

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:32

US3212004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	14 Dec 2020 14:52:32

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 14:52:38

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:52:42

US3212004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:42

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Dec 2020 14:52:47

US3212004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:12:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Afifah Ayub (b) (4)	14 Dec 2020 14:52:47

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:52
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 15:11:58
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:52
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:11:58
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:52
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:11:58
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	07 Dec 2020 15:11:58

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:12:15

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:12:15

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:12:15

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:12:15

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:58:56
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:15
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:12:15

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:00
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:19
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:00
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:19
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:03
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	07 Dec 2020 15:12:23
	(b) (4)	

US3212004

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:42:51

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 22:59:03
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 15:12:23
	(b) (4)	

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:07

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:07

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:07

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 17:52:07

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Heather Leary (b) (4)	22 Mar 2021 21:10:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:13:11

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4)	22 Mar 2021 21:10:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:13:11

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Placebo (Placebo)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Placebo (Placebo)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Placebo (Placebo)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '1'	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'I'	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered empty.	System	03 Mar 2021 19:03:31
DataPoint set to visible.	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered empty.	System	03 Mar 2021 19:03:31
DataPoint set to visible.	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	03 Mar 2021 19:03:31
	(b) (4)	

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '12:44'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '02 Mar 2021 12:44'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '98.1' F	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '76'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'bpm'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '16'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'breaths/min'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '134'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'mmHg'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '90'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'mmHg'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered missing code ND - Not Done.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered empty.	System	03 Mar 2021 19:03:31
DataPoint set to visible.	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '14:28'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '02 Mar 2021 14:28'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '97.6' F	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '78'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'bpm'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '16'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'breaths/min'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '126'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'mmHg'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '86'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'mmHg'	System	03 Mar 2021 19:03:31

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:41

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:03:41

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'mRNA-1273'	System	03 Mar 2021 19:04:13
DataPoint set to visible.	System	03 Mar 2021 17:52:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '13:43'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '02 Mar 2021 13:43'	System	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Left Arm (LEFT ARM)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'ONCE'	System	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 19:04:13

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
Signature has been broken.	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
Signature has been broken.	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User entered '02 Mar 2021' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:03
Signature has been broken.	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User entered '13:40' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Apr 2021 20:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:04:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '02 Mar 2021 13:40'	System	07 Apr 2021 20:50:40
User entered empty.	System	03 Mar 2021 19:04:26

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:05:02

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 06:02:46
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'please review PPD lab portal before issuing such queries. The specimen was received in lab on 04MAR2021 and produced a lab result on 05MAR2021. Ensure you double check the portal to reduce any unnecessary queries that weigh site metrics down, and waste everyone's time. ' (Site from DM).	Reagan Reed (b) (4)	08 Mar 2021 14:12:20
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 12:19:51
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:05:02

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '13:35'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:05:02

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:51

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered '02 Mar 2021 13:35'	System	03 Mar 2021 19:05:02

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Mar 2021 19:05:23

US3212004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:31:21
User entered 'I'	System	03 Mar 2021 19:05:23

US3212004

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	10 Mar 2021 17:47:09

US3212004

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '09 Mar 2021'	Laura Ngansop Djampou (b) (4)	10 Mar 2021 17:47:09

US3212004

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	10 Mar 2021 17:47:09

US3212004

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Laura Ngansop Djampou (b) (4)	10 Mar 2021 17:47:09

US3212004

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	10 Mar 2021 17:47:34

US3212004

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User entered 'I'	System	10 Mar 2021 17:47:34

US3212004

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:33
User entered '1'	System	10 Mar 2021 17:47:34
DataPoint set to visible.	System	10 Mar 2021 17:47:34

US3212004

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:39:11

US3212004

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '02 Apr 2021'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:39:11

US3212004

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:39:11

US3212004

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 13:39:11

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '02 Apr 2021'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '08:36'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 08:36'	System	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '97.3' F	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered empty.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '73'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '16'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '130'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '78'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:40:08

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '02 Apr 2021'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '11:35'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 11:35'	System	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '97.6' F	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered empty.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '61'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '16'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '126'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '80'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 13:40:41

US3212004

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:54

US3212004

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '02 Apr 2021'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:40:54

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered empty.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered empty.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	05 Apr 2021 13:41:19
DataPoint set to visible.	System	10 Mar 2021 17:47:34

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '02 Apr 2021'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered '11:00'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 11:00'	System	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Left Arm (LEFT ARM)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 13:41:19

US3212004

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:16:54
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	05 Apr 2021 13:41:52

US3212004

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:41:52

US3212004

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	12 Apr 2021 16:51:19

US3212004

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered '09 Apr 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	12 Apr 2021 16:51:19

US3212004

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	12 Apr 2021 16:51:19

US3212004

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	12 Apr 2021 16:51:19

US3212004

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 18:57:10
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	12 Apr 2021 16:51:29

US3212004

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:51:29

US3212004

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:30:57

US3212004

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '27 Apr 2021'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:30:57

US3212004

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:30:57

US3212004

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	28 Apr 2021 14:30:57

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '27 Apr 2021'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '08:42'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 08:42'	System	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '97.4' F	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered empty.	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '78'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '16'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '104'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '76'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 14:31:56

US3212004

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:32:09

US3212004

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '27 Apr 2021'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:32:09

US3212004

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:32:20

US3212004

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '27 Apr 2021'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:32:20

US3212004

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
User entered '09:50'	Laura Ngansop Djampou (b) (4)	28 Apr 2021 14:32:20

US3212004

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 09:50'	System	28 Apr 2021 14:32:20

US3212004

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:42:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:48
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	31 Aug 2020 16:33:36
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 14:00:15

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:47:48
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary FATIGUE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary FATIGUE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'Subject reported mild fatigue, muscle and joint aches starting at day 7. Subject retrained on diary compliance per source. The baseline injection was done on 03AUG2020 and these symptoms did not resolve until 11AUG2020. Per protocol: Any solicited AR that meets any of the following criteria must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF: Solicited local or systemic AR lasting beyond 7 days post injection. A solicited adverse reaction is still solicited even if it lasts longer than 7 days. ' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 14:46:16

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary FATIGUE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:24:06
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)	01 Sep 2020 02:40:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Sep 2020 02:40:38
Data point term sent to Coder	System	01 Sep 2020 02:39:38
User entered 'Fatigue (reactogenicity)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:02
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:10:34
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:47:04
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	23 Sep 2020 18:23:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 18:22:55
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:14:45
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:09
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:05
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:01:48
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	01 Sep 2020 02:39:22
User entered '09 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:12
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User entered empty.	System	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:14
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 02:51:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 02:51:09
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Sep 2020 02:51:09
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 02:39:22
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:16
User entered '11 Aug 2020'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:18
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User entered empty.	System	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:48:21
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:08
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:10
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:12
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:15
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:18
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:20
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:21
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:24
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:26
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:28
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:33
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:41:09
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:24:03
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:31:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 15:30:58
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:49:16
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:38
User entered 'None (NONE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:39
User entered 'I'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:44
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:43
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[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 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:46
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:48
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User entered '0'	System	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49
User entered '0'	System	01 Sep 2020 02:39:22

US3212004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:49

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:49:57
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary MUSCLE ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:23:23
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:20:11
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary MUSCLE ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'Subject reported mild fatigue, muscle and joint aches starting at day 7. Subject retrained on diary compliance per source. The baseline injection was done on 03AUG2020 and these symptoms did not resolve until 11AUG2020. Per protocol: Any solicited AR that meets any of the following criteria must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF: Solicited local or systemic AR lasting beyond 7 days post injection. A solicited adverse reaction is still solicited even if it lasts longer than 7 days. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 14:46:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

2710 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary MUSCLE ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:24:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 14:29:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 14:29:32
Data point term sent to Coder	System	10 Nov 2020 21:44:19
Query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'subject did not specify certain location of myalgia' (Site from DM).	Reagan Reed (b) (4)	10 Nov 2020 21:43:58
Coding entries removed.	Reagan Reed (b) (4)	10 Nov 2020 21:43:27
User entered 'Myalgia (REACTOGENICITY)' reason for change: Data Entry Error	Reagan Reed (b) (4)	10 Nov 2020 21:43:27
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:34:00
Query 'Per DM CLR: Please review AE and please update to specify the location of Arthralgia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:33:53
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Arthralgia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:33:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

2711 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:23:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:56:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 07:56:49
Data point term sent to Coder	System	01 Sep 2020 02:41:39
User entered 'Muscle Aches (reactogenicity)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:02
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:11:34
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:47:10
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	23 Sep 2020 18:24:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 18:23:26
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:15:23
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:05
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:08
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:01:56
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	01 Sep 2020 02:40:50
User entered '09 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:21
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User entered empty.	System	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:27
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:29
User entered '11 Aug 2020'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:30
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User entered empty.	System	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:33
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:35
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:37
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:39
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:40
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:42
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:43
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:44
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:46
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:47
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:48
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:53
User entered 'Related (RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 15:31:38
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:41:53
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:24:24
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:31:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 15:31:38
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:49:36
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:50:59
User entered 'None (NONE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:01
User entered 'I'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:03
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:05
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[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 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:08
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:10
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User entered '0'	System	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41
User entered '0'	System	01 Sep 2020 02:40:50

US3212004

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:52:41

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:21
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary JOINT ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:24:57
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Arthralgia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:24:54
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary JOINT ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'Subject reported mild fatigue, muscle and joint aches starting at day 7. Subject retrained on diary compliance per source. The baseline injection was done on 03AUG2020 and these symptoms did not resolve until 11AUG2020. Per protocol: Any solicited AR that meets any of the following criteria must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF: Solicited local or systemic AR lasting beyond 7 days post injection. A solicited adverse reaction is still solicited even if it lasts longer than 7 days.' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 14:46:32

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary JOINT ACHE Day 8 - Blank; Day 9 - NONE). Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:24:55
Query 'Per DM CLR: Please review AE and please update to specify the location of Arthralgia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'location unknown. ' (Site from DM).	Reagan Reed (b) (4)	10 Nov 2020 21:42:51
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Arthralgia. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:34:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 05:29:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 05:29:43
Data point term sent to Coder	System	01 Sep 2020 02:50:40
User entered 'Arthralgia (reactogenicity)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:25
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:11:41
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:47:13
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	23 Sep 2020 18:24:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 18:24:25
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:15:44
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:29
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:32
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:01:59
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	01 Sep 2020 02:50:25
User entered '09 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:33
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User entered empty.	System	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:35
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:51:37
User entered '11 Aug 2020'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:07
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User entered empty.	System	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:10
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:12
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:14
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:16
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:17
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:19
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:20
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:21
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:23
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:25
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:26
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:29
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:42:07
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:25:08
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:31:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 15:31:49
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:49:48
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:35
User entered 'None (NONE)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:36
User entered 'I'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:38
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:40
User entered '0'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[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 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:44
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:45
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User entered '0'	System	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02
User entered '0'	System	01 Sep 2020 02:50:25

US3212004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:02

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:31
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	09 Dec 2020 13:32:27

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:29:20
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 13:15:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	05 Apr 2021 13:15:41
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
Data point term sent to Coder	System	31 Mar 2021 21:03:44
DataPoint Un-verified.	Jagruti Patel (b) (4)	31 Mar 2021 21:03:41
Coding entries removed.	Jagruti Patel (b) (4)	31 Mar 2021 21:03:41
User entered 'COVID 19 (pneumonia)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	31 Mar 2021 21:03:41
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:53:57
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 18:38:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 18:38:32
Data point term sent to Coder	System	10 Dec 2020 17:28:42
Coding entries removed.	Reagan Reed (b) (4)	10 Dec 2020 17:28:35
User entered 'Covid 19 (DYSYPNEA)' reason for change: Data Entry Error	Reagan Reed (b) (4)	10 Dec 2020 17:28:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 19:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 19:22:43
Data point term sent to Coder	System	08 Dec 2020 19:21:34
Coding entries removed.	Reagan Reed (b) (4)	08 Dec 2020 19:21:33
User entered 'Dyspnea' reason for change: Data Entry Error	Reagan Reed (b) (4)	08 Dec 2020 19:21:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

2785 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 21:31:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 21:31:54
Data point term sent to Coder	System	07 Dec 2020 21:31:18
User entered 'SHORTNESS OF BREATH'	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:54:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:11:50
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:11:59
User closed query 'Per CDM: Please verify that indication is recorded as "COVID-19" however "is this event a confirmed diagnosis of symptomatic Covid-19?" is noted as NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 12:24:12
Query 'Per CDM: Please verify that indication is recorded as "COVID-19" however "is this event a confirmed diagnosis of symptomatic Covid-19?" is noted as NO. Please review and update accordingly. Else clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	29 Dec 2020 14:51:26
	(b) (4)	
DataPoint Un-verified.	Reagan Reed (b) (4)	29 Dec 2020 14:51:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:51:19
	(b) (4)	
User opened query 'Per CDM: Please verify that indication is recorded as "COVID-19" however "is this event a confirmed diagnosis of symptomatic Covid-19?" is noted as NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 13:55:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:54:25
	(b) (4), (b) (6)	
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:12:17
User closed query 'Per source, start date is 07Dec20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:41:52
Query 'Per source, start date is 07Dec20. Please verify and update accordingly.' answered with 'verified: symptoms began on 01DEC2020. Source and EDC now mirror one another ' (Site from CRA).	Reagan Reed (b) (4)	29 Dec 2020 14:51:55
User opened query 'Per source, start date is 07Dec20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 22:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 22:54:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:54:28
User closed query 'PV Query: SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (01Dec2020). If not updating the start date, please update symptom log.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:42:53
Query 'PV Query: SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (01Dec2020). If not updating the start date, please update symptom log.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	18 Dec 2020 15:43:23
User entered '01 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	17 Dec 2020 14:31:48
User opened query 'PV Query: SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (01Dec2020). If not updating the start date, please update symptom log.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:17:34
User entered '07 Dec 2020'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:12
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:14
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Dec 2020 22:09:35
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	22 Dec 2020 22:09:35
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Dec 2020 22:09:22
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:16
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		23 Dec 2020 15:13:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	22 Dec 2020 22:09:41
	(b) (4)	
User entered '17 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	22 Dec 2020 22:09:22
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:16:28
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:18
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Reagan Reed (b) (4)	08 Dec 2020 19:20:38
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Dec 2020 19:20:58
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Dec 2020 19:20:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	08 Dec 2020 19:20:38
User entered 'No (N)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:24
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:25
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 11:36:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'discharge date entered' (Site from System).	Reagan Reed (b) (4)	29 Dec 2020 14:53:07
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Dec 2020 17:14:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 09:38:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Reagan Reed (b) (4)	08 Dec 2020 19:21:03
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Dec 2020 19:20:58
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Dec 2020 19:20:58

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1' reason for change: Data Entry Error	System	08 Dec 2020 19:20:58
	Reagan Reed (b) (4)	08 Dec 2020 19:20:58
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	(b) (4) System	08 Dec 2020 19:20:38
	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:14:16
DataPoint Un-verified.	Laura Ngansop Djampou	28 Dec 2020 17:14:05
	(b) (4)	
User entered '07 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	28 Dec 2020 17:14:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:31
User entered '7 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	08 Dec 2020 19:20:38
	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:14:20
DataPoint Un-verified.	Reagan Reed (b) (4)	29 Dec 2020 14:52:57
	(b) (4)	
User entered '10 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:52:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:34
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:36
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:37
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:39
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:42
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:43
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:55:47
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:42:26
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:08
User closed query 'PV Query: Please consider updating the action taken with study drug to “not applicable” as per source, subject received both doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:42:24
Query 'PV Query: Please consider updating the action taken with study drug to “not applicable” as per source, subject received both doses of study drug.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	18 Dec 2020 15:44:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	18 Dec 2020 15:44:45
User opened query 'PV Query: Please consider updating the action taken with study drug to “not applicable” as per source, subject received both doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:17:13
User entered 'None (NONE)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:13
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:14
User entered 'I'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:20
User entered '0'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:24
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		23 Dec 2020 15:13:16
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	22 Dec 2020 22:09:46
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Reagan Reed (b) (4)	22 Dec 2020 22:09:22
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:16:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:25
User entered empty.	Afifah Ayub (b) (4)	07 Dec 2020 21:31:01
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA Medical query: Please clarify whether there is a single event of COVID-19 or two events of COVID-19 and COVID-19 pneumonia considering that the hospital records list both diagnoses.' answered with 'added' (Site from Safety).	Heather Leary (b) (4)	03 May 2021 14:24:24
User opened query 'IQVIA Medical query: Please clarify whether there is a single event of COVID-19 or two events of COVID-19 and COVID-19 pneumonia considering that the hospital records list both diagnoses.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 08:05:46
User closed query 'Per CDM: Response noted 'unable to enter medication until medical records are received.' Please update when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:41:00
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 15:06:47
User closed query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 15:06:44
Query 'Per CDM: Response noted 'unable to enter medication until medical records are received.' Please update when data becomes available. Thank you' answered with 'conmeds added. ' (Site from DM).	Jagruti Patel (b) (4)	01 Apr 2021 14:12:28
User opened query 'Per CDM: Response noted 'unable to enter medication until medical records are received.' Please update when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:05:37
Query 'Per CDM: Response noted 'unable to enter medication until medical records are received.' Please update when data becomes available. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:05:28
Comment added 'please close the query on medication as remdesivir has been added to conmeds.'.	Jagruti Patel (b) (4)	31 Mar 2021 22:14:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

2818 of 3188

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	Jagruti Patel (b) (4)	31 Mar 2021 22:12:59
Query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available ' answered with 'sent' (Site from Safety).	Jagruti Patel (b) (4)	31 Mar 2021 22:12:53
User opened query 'Per CDM: Response noted 'unable to enter medication until medical records are received.' Please update when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:49:47
User closed query 'Per DM CLR: Narrative indicates that the subject was started on Remdesivir. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:49:47
Query 'Per DM CLR: Narrative indicates that the subject was started on Remdesivir. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' answered with 'unable to enter medication until medical records are received. ' (Site from DM).	Reagan Reed (b) (4)	19 Jan 2021 14:31:23
User opened query 'Per DM CLR: Narrative indicates that the subject was started on Remdesivir. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:54:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:23:41

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 20:14:18
	(b) (4), (b) (6)	23 Dec 2020 22:56:45
User closed query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 15:13:23
User closed query 'PV Query: Per source documents, the subject was tested for COVID-19. Please provide all COVID-19 testing information and results.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 15:13:20
Query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available' answered with 'will submit when available ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	22 Dec 2020 22:10:46
Query 'PV Query: Per source documents, the subject was tested for COVID-19. Please provide all COVID-19 testing information and results.' answered with 'subjects study labs show positive results. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	22 Dec 2020 22:10:28
User opened query 'PV Query: Per case report, patient had an abnormal CT Chest. Kindly provide detailed report of chest CT when available' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:18:05
User opened query 'PV Query: Per source documents, the subject was tested for COVID-19. Please provide all COVID-19 testing information and results.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:16:50
User entered 'She has a history of mild asthma. She was having telehealth visits recently when she developed dyspnea and difficulty breathing. She went to the ER and she tested positive for COVID 19. She had an abnormal CT chest. She was admitted to the hospital and started on Remdesivir. Will follow her and request records.' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	08 Dec 2020 19:20:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 19:20:38
User entered '0'	System	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 21:31:01

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:29:43
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Liver function test increased, LLT: Raised LFTs - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 10:30:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 10:30:19
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
Data point term sent to Coder	System	01 Apr 2021 18:20:12
User entered 'Elevated LFTs' reason for change:	Laura Ngansop Djampou	01 Apr 2021 18:20:11
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	01 Apr 2021 13:33:02
User entered 'Elevated D Dimer'	Laura Ngansop Djampou	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:29:45
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:34
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:36
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '07 Dec 2020'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:37
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User entered empty.	System	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:41
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
Signature has been broken.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:57
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Apr 2021 18:20:11
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 14:15:53
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:15:53
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 14:01:41
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:45
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Apr 2021 20:33:57
Signature has been broken.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:57
User entered '05 Apr 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:57
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Apr 2021 20:33:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 18:20:11
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Apr 2021 18:20:11
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Apr 2021 18:20:11
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 18:17:35
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Apr 2021 14:01:41

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	01 Apr 2021 14:01:41
User entered '10 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:41
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	01 Apr 2021 14:01:19
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User entered empty.	System	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:50
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:55
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:56
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:36:58
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:00
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:03
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:04
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:06
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:08
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:10
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:11
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:14
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou	01 Apr 2021 18:20:11
reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou	01 Apr 2021 13:32:29
	(b) (4)	

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:20
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'None (NONE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Apr 2021 18:17:35
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:22
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Apr 2021 14:01:19
User entered '1' reason for change: Data Entry Error	Reagan Reed (b) (4)	01 Apr 2021 14:01:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Apr 2021 13:32:29
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:24
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:27
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:29
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:50:59
Signature has been broken.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Apr 2021 20:33:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Apr 2021 18:17:35
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 14:01:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 14:01:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	01 Apr 2021 14:01:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 13:32:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[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 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:32
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:37:34
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User entered '0'	System	01 Apr 2021 14:01:19

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04
User entered 'I'	System	01 Apr 2021 13:32:29

US3212004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:04

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Adverse event](#)

Audit	User	Time (GMT)
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)	03 May 2021 14:26:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 May 2021 14:26:20
Data point term sent to Coder	System	03 May 2021 14:24:45
User entered 'symptomatic covid-19'	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 Dec 2020'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Dec 2020'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Severity](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 14:24:05
User entered empty.	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Dec 2020'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Dec 2020'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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)	03 May 2021 17:14:35
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 14:24:05
User entered empty.	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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)	03 May 2021 17:14:45
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 14:24:05
User entered empty.	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[None](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Narrative](#)

Audit	User	Time (GMT)
User entered 'She has a history of mild asthma. She was having telehealth visits recently when she developed dyspnea and difficulty breathing. She went to the ER and she tested positive for COVID 19. She had an abnormal CT chest. She was admitted to the hospital and started on Remdesivir. Will follow her and request records.'	Heather Leary (b) (4)	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 14:24:05

US3212004

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:42:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 14:24:05

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:42:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:48
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:56:53
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 19:09:57

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:57:12
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:42:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:42:34
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 21:36:50
Coding entries removed.	Afifah Ayub (b) (4)	19 Oct 2020 21:36:10
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:15:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:15:09
	(b) (4)	
Data point term sent to Coder	System	04 Aug 2020 19:11:22
User entered 'Fluticasone Furoate/Vilanterol'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 17:42:26
	(b) (4), (b) (6)	
User closed query 'Per source, medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:42:20
Query 'Per source, medication is not taken for prophylaxis. Please verify and update accordingly.' answered with 'updated per source' (Site from CRA).	Reagan Reed (b) (4)	29 Dec 2020 14:49:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Dec 2020 14:49:01
User opened query 'Per source, medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 22:57:54
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:57:58
User entered 'mild ASTHMA' reason for change:	Afifah Ayub (b) (4)	19 Oct 2020 21:36:10
Data Entry Error	(b) (4)	
User entered 'Asthma'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:02
User entered '200/25'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:04
User entered 'ug (ug)'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:06
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:07
User entered 'once daily (QD)'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:09
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:11
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:13
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:15
	(b) (4), (b) (6)	06 Aug 2020 12:28:55
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).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Afifah Ayub (b) (4)	04 Aug 2020 21:14:31
answered with 'Subject is currently on the medication.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 19:11:19
User entered 'un UNK 2018'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:17
User entered '0'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:19
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:21
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:24
User entered 'No (N)'	Nirja Shah (b) (4)	04 Aug 2020 19:11:19
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:11:19

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:11:19

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 19:11:19

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS AND ESTROGENS IN COMBINATION, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:42:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:42:06
Data point term sent to Coder	System	04 Aug 2020 19:13:24
User entered 'Ethinylestradiol/Levonorgestrel'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:33
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	31 Aug 2020 13:53:50
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 21:15:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 21:15:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Aug 2020 21:15:41
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 19:12:27
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:12:27

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:36
User entered 'Menorrhagia'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:48
	(b) (4), (b) (6)	
User entered '0.03/0.15' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Oct 2020 15:19:38
	(b) (4)	
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:01:25
	(b) (4), (b) (6)	
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:18:01
	(b) (4), (b) (6)	
User entered '0.15/30' reason for change: Data Entry Error	Anna Pena (b) (4)	25 Sep 2020 20:17:28
	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:23:45
	(b) (4), (b) (6)	
User entered '0.15'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:50
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 07:19:39
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated to correct dose' (Site from DM).	Heather Leary (b) (4)	15 Oct 2020 15:19:46
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:32:54
	(b) (4)	
User entered 'mg (mg)'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:53
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:55
User entered 'once daily (QD)'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:57
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:58:59
User entered 'Oral (ORAL)'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:00
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:04
	(b) (4), (b) (6)	06 Aug 2020 12:29:03
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).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Afifah Ayub (b) (4)	04 Aug 2020 21:15:22
answered with 'Subject is currently on the medication.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 19:12:27
User entered 'un UNK 2017'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:12
User entered '0'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:14
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:15
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:18
User entered 'No (N)'	Nirja Shah (b) (4)	04 Aug 2020 19:12:27
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:12:27

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:12:27

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 19:12:27

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:42:51

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Per source, subject is taking or has taken since being enrolled in trial:	(b) (4), (b) (6)	31 Dec 2020 17:45:23
- Tylenol		
- Nyquil		
- Ibuprofen		
- Dexamethasone		
Please verify and update Con Med Log as applicable.'		
(Site from CRA).		
Query 'Per source, subject is taking or has taken since being enrolled in trial:	Reagan Reed (b) (4)	29 Dec 2020 14:49:33
- Tylenol	(b) (4)	
- Nyquil		
- Ibuprofen		
- Dexamethasone		
Please verify and update Con Med Log as applicable.'		
answered with 'All Medications have been entered into EDC accordingly ' (Site from CRA).		
User opened query 'Per source, subject is taking or has taken since being enrolled in trial:	(b) (4), (b) (6)	23 Dec 2020 23:02:36
- Tylenol		
- Nyquil		
- Ibuprofen		
- Dexamethasone		
Please verify and update Con Med Log as applicable.'		
(Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Aug 2020 19:16:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Aug 2020 19:16:03
	(b) (4)	

2932 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Aug 2020 19:14:27
User entered 'Albuterol'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:28
User entered 'No (N)'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:29
User entered 'Asthma'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:58
User entered '90'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:59:59
User entered 'ug (ug)'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:02
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:04
User entered 'as needed (PRN)'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:05
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:08
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:12
	(b) (4), (b) (6)	06 Aug 2020 12:29:12
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).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Afifah Ayub (b) (4)	04 Aug 2020 21:15:51
answered with 'Subject is currently on the medication.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 19:13:34
User entered 'un UNK 2013'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:13
User entered '0'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:15
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:17
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:00:19
User entered 'No (N)'	Nirja Shah (b) (4)	04 Aug 2020 19:13:34
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:13:34

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:13:34

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:13:34

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:45:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:45:20
Data point term sent to Coder	System	29 Dec 2020 14:44:05
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'Tylenol Extra Strength' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
Data point term sent to Coder	System	29 Dec 2020 14:43:03
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
Data point term sent to Coder	System	14 Sep 2020 20:22:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
Data point term sent to Coder	System	08 Sep 2020 15:01:37
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 14:57:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 14:57:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

2951 of 3188

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	08 Sep 2020 14:56:25
User entered 'Triamcinolone Acetonide'	Laura Ngansop Djampou	08 Sep 2020 14:55:38
	(b) (4)	

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'Covid-19' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'Eczema'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered '1000' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered '0.1%'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'mg (mg)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	08 Sep 2020 14:58:09
User entered '%' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:58:09
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	08 Sep 2020 14:55:38
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'as needed (PRN)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'as needed (PRN)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'Topical (TOPICAL)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '01 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:14:14
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Dec 2020 14:43:45
User entered '1 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered '31 Aug 2020'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 14:53:39
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Apr 2021 14:53:39
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
	(b) (4)	
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:58:19
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 14:53:39
User entered '20 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	28 Apr 2021 14:53:39
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	08 Sep 2020 14:58:19
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	08 Sep 2020 14:55:38
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:43:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:43:45
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:43:45
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:00:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:00:59
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User entered empty.	System	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4) (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4) (b) (4)	14 Sep 2020 20:21:30
User entered empty.	System	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:42:46
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:30
User entered empty.	System	08 Sep 2020 14:55:38

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: VICKS NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:47:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:47:19
Data point term sent to Coder	System	29 Dec 2020 14:45:07
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'Nyquil Cold & Flu (acetaminophen 500mg/doxylamine succinate 6.25mg/dextromethorphan HBr 15mg per 15mL)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
Data point term sent to Coder	System	14 Sep 2020 20:22:10
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
Data point term sent to Coder	System	08 Sep 2020 15:02:39
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
Data point term sent to Coder	System	08 Sep 2020 14:58:30
User entered 'Kenalog'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'Covid-19' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'Seborrhea'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered '30' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'UNK'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'mL (mL)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'UNK'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'as needed (PRN)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'as needed (PRN)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'Topical (TOPICAL)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '01 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:14:24
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Dec 2020 14:45:02
User entered '1 Dec 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered '31 Aug 2020'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 14:54:32
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Apr 2021 14:54:32
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:57:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 14:57:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:50
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:57:41
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	28 Apr 2021 22:23:19
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 14:54:32
User entered '15 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	28 Apr 2021 14:54:32
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 14:45:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:45:02
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:45:02
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:02:08
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Sep 2020 15:02:08
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	(b) (4)	
	System	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	(b) (4)	
	System	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:29
DataPoint activated with code reason code Data required.	Reagan Reed (b) (4)	29 Dec 2020 14:44:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Leary (b) (4)	14 Sep 2020 20:21:42
User entered empty.	(b) (4)	
	System	08 Sep 2020 14:57:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:49:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:49:17
Data point term sent to Coder User entered 'Ibuprofen'	System Reagan Reed (b) (4) (b) (4)	29 Dec 2020 14:48:10 29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Covid-19'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '200'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'mg (mg)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'once (ONCE)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (ORAL)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '01 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:14:37
User entered '1 Dec 2020'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '01 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	29 Dec 2020 17:14:37
User entered '1 Dec 2020'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User entered empty.	System	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User entered empty.	System	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:50
User entered empty.	System	29 Dec 2020 14:47:24

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
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: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:49:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:49:20
Data point term sent to Coder	System	29 Dec 2020 14:49:10
User entered 'dexamethasone'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Covid-19'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '4'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'mg (mg)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	29 Dec 2020 14:48:26
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	29 Dec 2020 14:48:26
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	29 Dec 2020 14:48:26
User entered 'other (OTHER)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Dec 2020 14:48:26
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	29 Dec 2020 14:48:16
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	29 Dec 2020 14:48:16
User entered 'once (ONCE)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '1.5 tablets daily'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'Oral (ORAL)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered empty.	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '10 Dec 2020'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '0'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '17 Dec 2020'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'No (N)'	Reagan Reed (b) (4)	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User entered empty.	System	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User entered empty.	System	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:26:56
User entered empty.	System	29 Dec 2020 14:48:16

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
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: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:22:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:22:39
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:16:31
Data point term sent to Coder	System	31 Mar 2021 22:06:57
User entered 'TV Decadron'	Jagruti Patel (b) (4) (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'COVID19 (Pneumonia)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '6'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'mg (mg)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'once daily (QD)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Intravenous (INTRAVENOUS)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '07 Dec 2020'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '10 Dec 2020'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User entered '1'	System	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User entered '1'	System	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:40
User entered '804 (804)'	System	31 Mar 2021 22:06:47

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:12:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:12:40
Data point term sent to Coder	System	31 Mar 2021 22:07:59
User entered 'TV Remdesivir'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'COVID19 (Pneumonia)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '100'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'mg (mg)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'as needed (PRN)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Intravenous (INTRAVENOUS)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '07 Dec 2020'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '0'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '10 Dec 2020'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'No (N)'	Jagruti Patel (b) (4)	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User entered empty.	System	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User entered empty.	System	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:47
User entered empty.	System	31 Mar 2021 22:07:41

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:42:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:48
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
DataPoint Un-verified.	Jagruti Patel (b) (4)	31 Mar 2021 22:04:55
Signature has been broken.	Jagruti Patel (b) (4)	31 Mar 2021 22:04:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Jagruti Patel (b) (4)	31 Mar 2021 22:04:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:04:03
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Aug 2020 18:13:21

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '07 Dec 2020'	Jagruti Patel (b) (4)	31 Mar 2021 22:05:24
	(b) (4)	

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'CT Chest with Contrast'	Jagruti Patel (b) (4)	31 Mar 2021 22:05:24
	(b) (4)	

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'Adverse Event (AE)'	Jagruti Patel (b) (4)	31 Mar 2021 22:05:24
	(b) (4)	

US3212004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:51

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered empty.	Jagruti Patel (b) (4)	31 Mar 2021 22:05:24
	(b) (4)	

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered '09/Dec/2020 13:32'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered '11/Dec/2020 11:39'	System	11 Dec 2020 16:39:38

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:43:51
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 16:39:38

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered '17/Dec/2020 13:02'	System	17 Dec 2020 18:02:55

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 18:02:59
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 18:02:55

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered '21/Dec/2020 09:44'	System	21 Dec 2020 14:44:05

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:22:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 14:44:05

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered '23/Dec/2020 10:13'	System	23 Dec 2020 15:13:45

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:22:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 15:13:45

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '29/Dec/2020 14:23'	System	29 Dec 2020 14:23:14

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 16:56:41
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 14:23:14

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered '29/Dec/2020 16:56'	System	29 Dec 2020 16:56:55

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 16:56:55

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered	System	09 Dec 2020 13:32:27
'USA-US115-2020-MRNA-1273-P301000015'		

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Yes (Y)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'No (N)'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Vicki'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 13:32:51
User entered 'Miller'	System	09 Dec 2020 13:32:27

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:21:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 22:46:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 16:39:06
User entered 'US'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	01 Apr 2021 12:56:22
User entered '7'	System	29 Dec 2020 16:56:55
User entered '6'	System	29 Dec 2020 14:23:14
User entered '5'	System	23 Dec 2020 15:13:45
User entered '4'	System	21 Dec 2020 14:44:05
User entered '3'	System	17 Dec 2020 18:02:55
User entered '2'	System	11 Dec 2020 16:39:38
User entered '1'	System	09 Dec 2020 13:32:57

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:42:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:24
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered '01/Apr/2021 05:56'	System	01 Apr 2021 12:56:22

US3212004

Folder: SAE USA-US115-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:42:51

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 10:58:24
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:16:31
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 12:56:22