

US3792080 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3792080

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

[Participant ID](#)

US3792080

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

US3792080

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	42
Age Units	YEARS
Age (Derived)	42
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

US3792080

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	30 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3792080

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3792080

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Were any significant conditions reported?

Yes ☒
No ☐

US3792080

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3792080

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3792080

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Condition	SEASONAL ASTHMA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3792080

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3792080

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Condition	TUBALLIGATION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3792080

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:36
Height (<i>xxx.x</i>)	70.8 in
Weight (<i>xxx.x</i>)	169.8 lb
BMI (<i>xxx.x</i>)	23.86608 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3792080

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Date of assessment (dd MMM yyyy) 30 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

US3792080

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	30 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3792080

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3792080

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3792080

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

What was the date of randomization? (dd MMM yyyy) 30 SEP 2020

What was the participant's randomization number? 115958

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Height	ND - Not Done
Weight	ND - Not Done

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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)	30 SEP 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:36
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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)	30 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:00
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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.

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 30 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 11:21 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 11:21

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

US3792080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	30 SEP 2020 10:45

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	30 SEP 2020 10:45
Nasopharyngeal Swab 2	No		

US3792080

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	30 SEP 2020 12:04
PC Open Date & Time	30 SEP 2020 11:41
PC Close Date & Time	30 SEP 2020 14:11

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 98.7 °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	30 SEP 2020 18:05
PC Open Date & Time	30 SEP 2020 15:06
PC Close Date & Time	01 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:04

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

97.9 °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

02 OCT 2020 12:22

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:36

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

04 OCT 2020 13:12

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 OCT 2020 12:19

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

98.2 °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 OCT 2020 12:17

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

30 SEP 2020 12:04

PC Open Date & Time

30 SEP 2020 11:41

PC Close Date & Time

30 SEP 2020 14:11

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

30 SEP 2020 18:07

PC Open Date & Time

30 SEP 2020 15:06

PC Close Date & Time

01 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 12:22

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 12:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 13:13

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 12:19

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 OCT 2020 12:15

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 12:06
PC Open Date & Time	30 SEP 2020 11:41
PC Close Date & Time	30 SEP 2020 14:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 18:07
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PC Open Date & Time	30 SEP 2020 15:06
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PC Close Date & Time	01 OCT 2020 11:59
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US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 3053

EAB) (1725)

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:23
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:33
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

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)

56 of 3053

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 13:13
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 3053

EAB) (1725)

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:20
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3053

EAB) (1725)

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:16
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 8

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 07 OCT 2020 12:00

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

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	07 OCT 2020 12:01
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PC Open Date & Time	07 OCT 2020 12:00
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PC Close Date & Time	08 OCT 2020 11:59
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US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

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 08 OCT 2020 12:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 10

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 09 OCT 2020 13:09

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 12:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

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	08 OCT 2020 12:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 13:09
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3792080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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)	4 NOV 2020
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 09:33
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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)	4 NOV 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 10:36
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

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

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	4 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

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) 4 NOV 2020

What was the treatment time? (00:00-23:59) 10:02 (24 HR)

Treatment Date and Time (derived) 4 NOV 2020 10:02

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

US3792080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 NOV 2020

Collection time (00:00-23:59)

09:38 (24 HR)

Collection date and time (derived)

4 NOV 2020 09:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Collection date (dd MMM yyyy)			4 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:43	4 NOV 2020 09:43
Nasopharyngeal Swab 2	No		

US3792080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

04 NOV 2020 10:37

PC Open Date & Time

04 NOV 2020 10:22

PC Close Date & Time

04 NOV 2020 12:52

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 NOV 2020 13:47

PC Close Date & Time 05 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

98.3 °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

05 NOV 2020 17:36

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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

06 NOV 2020 12:14

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

98.6 °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

07 NOV 2020 17:08

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

98.7 °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

08 NOV 2020 13:21

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 NOV 2020 19:04

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

98.3 °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

10 NOV 2020 17:36

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 10:38

PC Open Date & Time

04 NOV 2020 10:22

PC Close Date & Time

04 NOV 2020 12:52

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 NOV 2020 13:47

PC Close Date & Time

05 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

05 NOV 2020 17:36

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

06 NOV 2020 12:12

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

07 NOV 2020 17:08

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

08 NOV 2020 13:21

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

09 NOV 2020 19:04

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

10 NOV 2020 17:36

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

No ☒

Yes ☐

PC Time stamp	04 NOV 2020 10:38
PC Open Date & Time	04 NOV 2020 10:22
PC Close Date & Time	04 NOV 2020 12:52

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 NOV 2020 13:47

PC Close Date & Time

05 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	05 NOV 2020 17:37
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 17:08
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

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)

110 of 3053

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	08 NOV 2020 13:21
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	09 NOV 2020 19:05
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 ☒

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

Yes <input type="checkbox"/>	
PC Time stamp	10 NOV 2020 17:36
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3792080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A VOICEMAIL ASKED HER
TO CALL ME BACK

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:01 (24 HR)
Vital Signs Date and Time (derived)	9 DEC 2020 11:01
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 DEC 2020

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

US3792080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 DEC 2020

Collection time (00:00-23:59)

11:09 (24 HR)

Collection date and time (derived)

9 DEC 2020 11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:14

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 00:03:16

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 DEC 2020 00:01:36
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

11 DEC 2020 03:49:50

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

22 DEC 2020 16:46:22

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 JAN 2021 00:01:24
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 00:57:06

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

22 JAN 2021 00:06:57

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 03:05:05

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

14 FEB 2021 01:21:31

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 19:18:21

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

26 FEB 2021 08:46:58

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

07 MAR 2021 21:07:38

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

12 MAR 2021 00:01:25

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

19 MAR 2021 08:26:55

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

29 MAR 2021 09:21:27

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 APR 2021 17:40:34

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

09 APR 2021 18:19:38

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

23 APR 2021 00:57:16

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:14:59

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	28 SEP 2021 23:59
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US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 <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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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°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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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°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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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°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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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°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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 <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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 DEC 2022 00:01
Patient Cloud Close Date & Time	06 DEC 2022 23:59

US3792080

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:49:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 10:40:39

US3792080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:09

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 APR 2021
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	30 APR 2021 11:43
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

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.

US3792080

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 APR 2021
Collection time (00:00-23:59)	12:07 (24 HR)
Collection date and time (derived)	30 APR 2021 12:07

US3792080

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Apr 2021 16:13:23

Generated On: 10 Jun 2021 09:49:54

Date of Contact	3 DEC 2020
Time of Contact	09:30
Date and Time of Contact (derived)	3 DEC 2020 09:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	3 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	4 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.7 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

346 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)

350 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	97 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	98 %
---------------	------

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

Temperature	98.9 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	98 %	
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)

366 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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)

374 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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)

386 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	9 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)

394 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

	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	<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)

398 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

399 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Date of Visit	3 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	5 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input checked="" 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)	1

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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)

402 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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)

403 of 3053

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Date of Contact	3 DEC 2020
Time of Contact	09:30
Date and Time of Contact (derived)	3 DEC 2020 09:30
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"/>

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Date of Visit	3 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	3 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	5 DEC 2020
Day 5	Yes	7 DEC 2020
Day 7	No	
Day 9	Yes	11 DEC 2020
Day 14	Yes	16 DEC 2020
Day 21	Yes	23 DEC 2020
Day 28	Yes	30 DEC 2020

US3792080

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 10 Jun 2021 09:49:54

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	09:44 (24 HR)
Vital Signs Date and Time (derived)	3 DEC 2020 09:44
Height (<i>xxx.x</i>)	70.75 in
Weight (<i>xxx.x</i>)	172.0 lb
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 DEC 2020

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

US3792080

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

3 DEC 2020

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 APR 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 11:40
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 APR 2021

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

US3792080

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 APR 2021

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 DEC 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 09:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3792080

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 DEC 2020

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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 _____

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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)	

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

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.

US3792080

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:49:54

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	
--------------------	--

US3792080

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3792080

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Date of updated informed consent (<i>dd MMM yyyy</i>)	29 JAN 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>)	29 JAN 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

US3792080

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Height	
Weight	
BMI (xxx.x)	

US3792080

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Height	
Weight	
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)	29 JAN 2021
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 10:21
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)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Height	
Weight	
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)	29 JAN 2021
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 11:59
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 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)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

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.

US3792080

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

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 29 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3792080

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

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) 29 JAN 2021

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

Treatment Date and Time (derived) 29 JAN 2021 11:28

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

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

US3792080

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

29 JAN 2021 10:30

US3792080

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	10:35
Collection Date and Time (derived)	29 JAN 2021 10:35

US3792080

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:08

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:13

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3792080

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

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)	26 FEB 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:30
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)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

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)	26 FEB 2021
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 10:47
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)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3792080

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

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.

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Apr 2021 16:13:23

Generated On: 10 Jun 2021 09:49:54

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 FEB 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3792080

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:15

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

US3792080

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792080

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:54:30

Generated On: 10 Jun 2021 09:49:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792080

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:40 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 11:40
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792080

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 APR 2021

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

US3792080

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 22:50:53

Generated On: 10 Jun 2021 09:49:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 APR 2021
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	2 APR 2021 12:15

US3792080

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 16:13:23

Generated On: 10 Jun 2021 09:49:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

AEID

Adverse event

COMMON COLD

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 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

453 of 3053

EAB) (1725)

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	HAD COVID 19 TEST DONE AND IT WAS NEGATIVE
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)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

AEID	USA-US057-2020-MRNA-1273-P30 1000003
Adverse event	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)	3 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)	31 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	455 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input 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	SUBJECT HAD A NEGATIVE PCR SWAB BUT DAY 3 SALIVA WAS POSITIVE.
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)	

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

AEID

Adverse event

MINOR CANKER SORE, LEFT
LATERAL TONGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

457 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

AEID

Adverse event

ARTHRALGIA

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 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 OCT 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

EAB) (1725)

459 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	AE REPORTED PER EDC QUERY AS SUBJECT REPORTED THIS IN HER DIARY AND NOT TO THE SITE AT A CLINIC VISIT
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)	

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

AEID	
Adverse event	WORSENER SEASONAL ALLERGIES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

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

Yes ☒

No ☐

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

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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

464 of 3053

EAB) (1725)

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

466 of 3053

EAB) (1725)

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication MUSINEX ER

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 750

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

468 of 3053

EAB) (1725)

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication SEASONAL 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)

470 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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 2010	
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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

472 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input 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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication TYLENOLD COLD
ACETAMINOPHEN/DEXTROMET
HORPHAN

Prophylaxis Yes ☐
No ☒

Indication COMMON COLD

Dose per administration 325/10

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 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication TYLENOL COLD AND FLU
ACETAMINOPHEN/DEXTROMET
HORPHAN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 325/10

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 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)	3 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)	04 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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

478 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)		05 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)		21 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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication VITAMIN D DEFICIENCY
PROPHYLAXIS

Dose per administration 2000

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)

480 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication VITAMIN B DEFICIENCY
PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

482 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication WORSENE SEASONAL
ALLERGIES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

484 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)		31 MAR 2021
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication DEXTROMETHORPHAN

Prophylaxis Yes ☐
No ☒

Indication WORSENE SEASONAL
ALLERGIES

Dose per administration 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)

486 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)		09 APR 2021
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"/>

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

Name of Medication ALLEGRA -D
FEXOFENADINE
HCL/PSEUDOPHENEDRINE HCL

Prophylaxis Yes ☐
No ☒

Indication WORSENE SEASONAL
ALLERGIES

Dose per administration 180/240

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

488 of 3053

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 17:06:48

Generated On: 10 Jun 2021 09:49:54

	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)	09 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 APR 2021	
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"/>

US3792080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 21:59:07

Generated On: 10 Jun 2021 09:49:54

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3792080

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:49:54

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

US3792080

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:49:54

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 ☐

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/DEC/2020 10:01
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

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/DEC/2020 11:02
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

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/JAN/2021 10:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/FEB/2021 10:10
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

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/FEB/2021 09:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/APR/2021 15:35
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

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/APR/2021 14:34
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

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 05:43:57

Generated On: 10 Jun 2021 09:49:54

SAEID	USA-US057-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/APR/2021 10:16
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

US3792080 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3792080

Form: Participant Creation

Generated On: 10 Jun 2021 09:49:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'US3792080'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 16:47:56

US3792080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:59

US3792080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 16:47:57

US3792080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:59

US3792080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'SCRN'	System	30 Sep 2020 18:35:59

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered (b) (6) 1977'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 16:47:58

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '42'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'YEARS'	System	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '42'	System	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Female (F)'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'I'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:36:20

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:59:34
User entered '30 Sep 2020'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Sep 2020'	System	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '2020'	System	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:59:35
User entered 'Amendment 3 (3)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:59:37
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:59:39
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:36:38

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 16:47:57

US3792080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'I'	System	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:01:13
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:49:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:36:49

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:26
Data point term sent to Coder	System	30 Sep 2020 19:44:32
User entered 'Depression'	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'un UNK 1990'	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Jan 1990'	System	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '1990'	System	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:43:38

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:28
Data point term sent to Coder	System	30 Sep 2020 19:44:32
User entered 'seasonal allergies'	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'un UNK 1999'	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Jan 1999'	System	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '1999'	System	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:43:56

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Seasonal asthma - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:28
Data point term sent to Coder	System	30 Sep 2020 19:44:32
User entered 'seasonal asthma'	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'un UNK 2010'	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Jan 2010'	System	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '2010'	System	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:44:19

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 19:46:40
Data point term sent to Coder	System	30 Sep 2020 19:45:33
User entered 'allergy to sulfa'	Norma Frederick (b) (4)	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	30 Sep 2020 19:45:28
User entered 'UN UNK 1998' reason for change: Data Entry Error	System	30 Sep 2020 19:45:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Norma Frederick (b) (4)	30 Sep 2020 19:45:28
User entered 'un 1998' (non-conformant).	(b) (4)	30 Sep 2020 19:44:39
	System	30 Sep 2020 19:44:39
	Norma Frederick (b) (4)	30 Sep 2020 19:44:39
	(b) (4)	

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Jan 1998'	System	30 Sep 2020 19:45:28
User entered empty.	System	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '1998'	System	30 Sep 2020 19:45:28
User entered empty.	System	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:44:39

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 12:46:59
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:17:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:20:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:20:39
Data point term sent to Coder	System	30 Sep 2020 19:45:33
User entered 'tuballigation'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'un UNK 2014'	Norma Frederick (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:40:53
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:16:43
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'Jan 2014'	System	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '2014'	System	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:45:00

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '10:36'	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '30 Sep 2020 10:36'	System	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '70.8' in	(b) (4)	
	Norma Frederick (b) (4)	30 Sep 2020 19:42:56
DataPoint set to visible.	(b) (4)	
	System	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '169.8' lb	Norma Frederick (b) (4)	30 Sep 2020 19:42:56
DataPoint set to visible.	System	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '23.86608'	System	30 Sep 2020 19:42:56
DataPoint set to visible.	System	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'kg/m2'	System	30 Sep 2020 19:42:56
DataPoint set to visible.	System	30 Sep 2020 18:36:43

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'bpm'	System	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'breaths/min'	System	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	30 Sep 2020 19:42:56

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19

US3792080

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Per CDM: Please consider updating Was the Physical examination performed? Yes . Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 09:58:01
Query 'Per CDM: Please consider updating Was the Physical examination performed? Yes . Thank you.' answered with 'Done' (Site from DM).	Ann Marie Milliken (b) (4)	18 Nov 2020 20:26:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Ann Marie Milliken (b) (4)	18 Nov 2020 20:25:23
User opened query 'Per CDM: Please consider updating Was the Physical examination performed? Yes . Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:01:57
Query 'Per CDM: Please consider updating Was the Physical examination performed? Yes . Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 05:00:15
User opened query 'Per CDM: Please consider updating Was the Physical examination performed? Yes . Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 04:57:25
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:39:09

US3792080

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '30 Sep 2020' reason for change: Data Entry Error	System	18 Nov 2020 20:26:34
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	Ann Marie Milliken	18 Nov 2020 20:26:34
User entered empty.	(b) (4)	
	(b) (4)	
	System	18 Nov 2020 20:25:23
	Norma Frederick (b) (4)	30 Sep 2020 18:39:09
	(b) (4)	

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:49:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:05

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Urine (URINE)'	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Negative (NEGATIVE)'	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	30 Sep 2020 19:45:54

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'I'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:32

US3792080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:49

US3792080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:35:49

US3792080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[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 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:49

US3792080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'VISIT1'	System	30 Sep 2020 18:35:49

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 17:53:03

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '115958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 17:53:03

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 17:53:03

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:16

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:16

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:16

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:16

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:35:16

US3792080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	(b) (4)	
	Norma Frederick (b) (4)	30 Sep 2020 19:46:06
DataPoint set to visible.	(b) (4)	
	System	30 Sep 2020 18:36:38

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '10:36'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered '30 Sep 2020 10:36'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '98.6' F	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '51'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'bpm'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '14'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'breaths/min'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '116'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'mmHg'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '78'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'mmHg'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '12:00'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '99.1' F	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '50'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'bpm'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '16'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'breaths/min'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '126'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'mmHg'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '78'	Norma Frederick (b) (4)	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'mmHg'	System	30 Sep 2020 19:48:29

US3792080

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Per CDM: Subject was screened and dosed on same day Please consider updating 'Was the physical examination and pregnancy test performed ?' to No at Visit 1 Day 1 and Yes at Screening for Physical examination,as childbearing potential is Yes. Alternatively, please explain ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 09:57:49
Query 'Per CDM: Subject was screened and dosed on same day Please consider updating 'Was the physical examination and pregnancy test performed ?' to No at Visit 1 Day 1 and Yes at Screening for Physical examination,as childbearing potential is Yes. Alternatively, please explain ' answered with 'Done' (Site from DM).	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 20:27:18
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:27:10
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:26:59
User entered 'No (N)' reason for change: Data Entry Error	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 20:26:59
User opened query 'Per CDM: Subject was screened and dosed on same day Please consider updating 'Was the physical examination and pregnancy test performed ?' to No at Visit 1 Day 1 and Yes at Screening for Physical examination,as childbearing potential is Yes. Alternatively, please explain ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 05:00:08
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 18:37:44

US3792080

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty; reason for change Data Entry Error	Ann Marie Milliken (b) (4)	18 Nov 2020 20:27:10
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:37:44

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Urine (URINE)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Negative (NEGATIVE)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered empty.	System	30 Sep 2020 18:37:57

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '11:21'	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered '30 Sep 2020 11:21'	System	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'ONCE'	System	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 18:38:24

US3792080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:36

US3792080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:38:36

US3792080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Nov 2020 20:26:38
User entered '10:45' reason for change: Data Entry Error	Norma Frederick (b) (4)	12 Nov 2020 20:26:38
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 18:38:36
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:38:36

US3792080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered '30 Sep 2020 10:45'	System	12 Nov 2020 20:26:38
User entered empty.	System	30 Sep 2020 18:38:36

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Sep 2020'	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	12 Nov 2020 20:27:09
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	12 Nov 2020 20:27:09
User entered '10:45' reason for change: Data Entry Error	Norma Frederick (b) (4)	12 Nov 2020 20:27:09
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	30 Sep 2020 18:38:50
User entered empty.	System	30 Sep 2020 18:38:50
	Norma Frederick (b) (4)	30 Sep 2020 18:38:50
	(b) (4)	

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered '30 Sep 2020 10:45'	System	12 Nov 2020 20:27:09
User entered empty.	System	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered empty.	System	30 Sep 2020 18:38:50

US3792080

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 18:38:56

US3792080

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'I'	System	30 Sep 2020 18:38:56

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:03:25', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '28519f22-fcba-4f62-8eb2-c4427b0d9d19'	System	30 Sep 2020 19:04:08
User entered 'Yes (Y)'	System	30 Sep 2020 19:04:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:03:29', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '28519f22-fcba-4f62-8eb2-c4427b0d9d19'	System	30 Sep 2020 19:04:08
User entered '99.1'	System	30 Sep 2020 19:04:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:03:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '28519f22-fcba-4f62-8eb2-c4427b0d9d19'	System	30 Sep 2020 19:04:08
User entered 'No (N)'	System	30 Sep 2020 19:04:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:03', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '28519f22-fcba-4f62-8eb2-c4427b0d9d19'	System	30 Sep 2020 19:04:08
User entered '30 Sep 2020 12:04'	System	30 Sep 2020 19:04:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 14:11'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:05:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '04c440df-b6a0-47ff-afba-0606bb64e7aa'	System	01 Oct 2020 01:05:51
User entered 'Yes (Y)'	System	01 Oct 2020 01:05:51

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:05:39', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '04c440df-b6a0-47ff-afba-0606bb64e7aa'	System	01 Oct 2020 01:05:51
User entered '98.7'	System	01 Oct 2020 01:05:51

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:05:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '04c440df-b6a0-47ff-afba-0606bb64e7aa'	System	01 Oct 2020 01:05:51
User entered 'No (N)'	System	01 Oct 2020 01:05:51

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:05:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '04c440df-b6a0-47ff-afba-0606bb64e7aa'	System	01 Oct 2020 01:05:51
User entered '30 Sep 2020 18:05'	System	01 Oct 2020 01:05:51

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 15:06'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 2'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:03:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3d028c95-717d-4f36-8820-0c4bf091bdf1'	System	01 Oct 2020 19:04:11
User entered 'Yes (Y)'	System	01 Oct 2020 19:04:11

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:03:58', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3d028c95-717d-4f36-8820-0c4bf091bdf1'	System	01 Oct 2020 19:04:11
User entered '97.4'	System	01 Oct 2020 19:04:11

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:04:01', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3d028c95-717d-4f36-8820-0c4bf091bdf1'	System	01 Oct 2020 19:04:11
User entered 'No (N)'	System	01 Oct 2020 19:04:11

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:04:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3d028c95-717d-4f36-8820-0c4bf091bdf1'	System	01 Oct 2020 19:04:11
User entered '01 Oct 2020 12:04'	System	01 Oct 2020 19:04:11

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 3'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:01', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cab6936-b466-4e92-a036-6d7fe5e19212'	System	02 Oct 2020 19:22:17
User entered 'Yes (Y)'	System	02 Oct 2020 19:22:17

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cab6936-b466-4e92-a036-6d7fe5e19212'	System	02 Oct 2020 19:22:17
User entered '97.9'	System	02 Oct 2020 19:22:17

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cab6936-b466-4e92-a036-6d7fe5e19212'	System	02 Oct 2020 19:22:17
User entered 'No (N)'	System	02 Oct 2020 19:22:17

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cab6936-b466-4e92-a036-6d7fe5e19212'	System	02 Oct 2020 19:22:17
User entered '02 Oct 2020 12:22'	System	02 Oct 2020 19:22:17

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 4'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:34:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a50479fa-3d96-4c03-b6ba-dd9c86a81e46'	System	03 Oct 2020 19:36:08
User entered 'Yes (Y)'	System	03 Oct 2020 19:36:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:35:58', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a50479fa-3d96-4c03-b6ba-dd9c86a81e46'	System	03 Oct 2020 19:36:08
User entered '97.9'	System	03 Oct 2020 19:36:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:36:01', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a50479fa-3d96-4c03-b6ba-dd9c86a81e46'	System	03 Oct 2020 19:36:08
User entered 'No (N)'	System	03 Oct 2020 19:36:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:36:06', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a50479fa-3d96-4c03-b6ba-dd9c86a81e46'	System	03 Oct 2020 19:36:08
User entered '03 Oct 2020 12:36'	System	03 Oct 2020 19:36:08

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 5'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:27', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cd87e74-3ac6-45fb-a0d0-a243b9fbc1bb'	System	04 Oct 2020 20:12:44
User entered 'Yes (Y)'	System	04 Oct 2020 20:12:44

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cd87e74-3ac6-45fb-a0d0-a243b9fbc1bb'	System	04 Oct 2020 20:12:44
User entered '97.9'	System	04 Oct 2020 20:12:44

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cd87e74-3ac6-45fb-a0d0-a243b9fbc1bb'	System	04 Oct 2020 20:12:44
User entered 'No (N)'	System	04 Oct 2020 20:12:44

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:41', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5cd87e74-3ac6-45fb-a0d0-a243b9fbc1bb'	System	04 Oct 2020 20:12:44
User entered '04 Oct 2020 13:12'	System	04 Oct 2020 20:12:44

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 6'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd0ed8e2a-d252-42dd-a347-e11de599d265'	System	05 Oct 2020 19:19:22
User entered 'Yes (Y)'	System	05 Oct 2020 19:19:22

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd0ed8e2a-d252-42dd-a347-e11de599d265'	System	05 Oct 2020 19:19:22
User entered '97.8'	System	05 Oct 2020 19:19:22

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:17', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd0ed8e2a-d252-42dd-a347-e11de599d265'	System	05 Oct 2020 19:19:22
User entered 'No (N)'	System	05 Oct 2020 19:19:22

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:20', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd0ed8e2a-d252-42dd-a347-e11de599d265'	System	05 Oct 2020 19:19:22
User entered '05 Oct 2020 12:19'	System	05 Oct 2020 19:19:22

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 7'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:17:07', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd390913d-be9a-4c4c-b023-bf4f2cdc8c7b'	System	06 Oct 2020 19:21:04
User entered 'Yes (Y)'	System	06 Oct 2020 19:21:04

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:17:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd390913d-be9a-4c4c-b023-bf4f2cdc8c7b'	System	06 Oct 2020 19:21:04
User entered '98.2'	System	06 Oct 2020 19:21:04

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:17:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd390913d-be9a-4c4c-b023-bf4f2cdc8c7b'	System	06 Oct 2020 19:21:04
User entered 'No (N)'	System	06 Oct 2020 19:21:04

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:17:17', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd390913d-be9a-4c4c-b023-bf4f2cdc8c7b'	System	06 Oct 2020 19:21:04
User entered '06 Oct 2020 12:17'	System	06 Oct 2020 19:21:04

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'e9d8c995-1884-4e63-b08a-b4e50b6f6e5d'	System	30 Sep 2020 19:05:02
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 19:05:02

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'e9d8c995-1884-4e63-b08a-b4e50b6f6e5d'	System	30 Sep 2020 19:05:02
User entered 'No (N)'	System	30 Sep 2020 19:05:02

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:47', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'e9d8c995-1884-4e63-b08a-b4e50b6f6e5d'	System	30 Sep 2020 19:05:02
User entered 'No (N)'	System	30 Sep 2020 19:05:02

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:52', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'e9d8c995-1884-4e63-b08a-b4e50b6f6e5d'	System	30 Sep 2020 19:05:02
User entered 'None (1)'	System	30 Sep 2020 19:05:02

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:04:57', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'e9d8c995-1884-4e63-b08a-b4e50b6f6e5d'	System	30 Sep 2020 19:05:02
User entered '30 Sep 2020 12:04'	System	30 Sep 2020 19:05:02

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 14:11'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:05:56', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '958b7bbb-9689-4b94-b0e0-a7df6e11657f'	System	01 Oct 2020 01:07:03
User entered 'None (1)'	System	01 Oct 2020 01:07:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:06:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '958b7bbb-9689-4b94-b0e0-a7df6e11657f'	System	01 Oct 2020 01:07:03
User entered 'No (N)'	System	01 Oct 2020 01:07:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:06:29', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '958b7bbb-9689-4b94-b0e0-a7df6e11657f'	System	01 Oct 2020 01:07:03
User entered 'No (N)'	System	01 Oct 2020 01:07:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:06:55', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '958b7bbb-9689-4b94-b0e0-a7df6e11657f'	System	01 Oct 2020 01:07:03
User entered 'None (1)'	System	01 Oct 2020 01:07:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:01', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '958b7bbb-9689-4b94-b0e0-a7df6e11657f'	System	01 Oct 2020 01:07:03
User entered '30 Sep 2020 18:07'	System	01 Oct 2020 01:07:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 15:06'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 2'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:00:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5754415b-45c2-4fb0-9101-e0b6868fddbde'	System	01 Oct 2020 19:01:28
User entered 'None (1)'	System	01 Oct 2020 19:01:28

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:00:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5754415b-45c2-4fb0-9101-e0b6868fddbe'	System	01 Oct 2020 19:01:28
User entered 'No (N)'	System	01 Oct 2020 19:01:28

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:00:56', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5754415b-45c2-4fb0-9101-e0b6868fddb'	System	01 Oct 2020 19:01:28
User entered 'No (N)'	System	01 Oct 2020 19:01:28

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:00:59', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5754415b-45c2-4fb0-9101-e0b6868fddbde'	System	01 Oct 2020 19:01:28
User entered 'None (1)'	System	01 Oct 2020 19:01:28

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5754415b-45c2-4fb0-9101-e0b6868fddbde'	System	01 Oct 2020 19:01:28
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 19:01:28

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 3'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1e454fa-ead2-4276-856f-c98b5d73e6f7'	System	02 Oct 2020 19:22:38
User entered 'None (1)'	System	02 Oct 2020 19:22:38

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:24', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1e454fa-ead2-4276-856f-c98b5d73e6f7'	System	02 Oct 2020 19:22:38
User entered 'No (N)'	System	02 Oct 2020 19:22:38

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:26', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1e454fa-ead2-4276-856f-c98b5d73e6f7'	System	02 Oct 2020 19:22:38
User entered 'No (N)'	System	02 Oct 2020 19:22:38

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:30', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1e454fa-ead2-4276-856f-c98b5d73e6f7'	System	02 Oct 2020 19:22:38
User entered 'None (1)'	System	02 Oct 2020 19:22:38

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:33', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1e454fa-ead2-4276-856f-c98b5d73e6f7'	System	02 Oct 2020 19:22:38
User entered '02 Oct 2020 12:22'	System	02 Oct 2020 19:22:38

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 4'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:32:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '507250a0-a513-47a1-8f32-6dc0faa569a7'	System	03 Oct 2020 19:32:59
User entered 'None (1)'	System	03 Oct 2020 19:32:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:32:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '507250a0-a513-47a1-8f32-6dc0faa569a7'	System	03 Oct 2020 19:32:59
User entered 'No (N)'	System	03 Oct 2020 19:32:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:32:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '507250a0-a513-47a1-8f32-6dc0faa569a7'	System	03 Oct 2020 19:32:59
User entered 'No (N)'	System	03 Oct 2020 19:32:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:32:52', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '507250a0-a513-47a1-8f32-6dc0faa569a7'	System	03 Oct 2020 19:32:59
User entered 'None (1)'	System	03 Oct 2020 19:32:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:32:56', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '507250a0-a513-47a1-8f32-6dc0faa569a7'	System	03 Oct 2020 19:32:59
User entered '03 Oct 2020 12:32'	System	03 Oct 2020 19:32:59

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 5'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:46', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd036317d-5833-49e9-9e48-0b752498de14'	System	04 Oct 2020 20:13:03
User entered 'None (1)'	System	04 Oct 2020 20:13:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:49', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd036317d-5833-49e9-9e48-0b752498de14'	System	04 Oct 2020 20:13:03
User entered 'No (N)'	System	04 Oct 2020 20:13:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd036317d-5833-49e9-9e48-0b752498de14'	System	04 Oct 2020 20:13:03
User entered 'No (N)'	System	04 Oct 2020 20:13:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:12:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd036317d-5833-49e9-9e48-0b752498de14'	System	04 Oct 2020 20:13:03
User entered 'None (1)'	System	04 Oct 2020 20:13:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd036317d-5833-49e9-9e48-0b752498de14'	System	04 Oct 2020 20:13:03
User entered '04 Oct 2020 13:13'	System	04 Oct 2020 20:13:03

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 6'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:34', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c2c08264-2296-4dea-afde-43557db5d793'	System	05 Oct 2020 19:19:50
User entered 'None (1)'	System	05 Oct 2020 19:19:50

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c2c08264-2296-4dea-afde-43557db5d793'	System	05 Oct 2020 19:19:50
User entered 'No (N)'	System	05 Oct 2020 19:19:50

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:39', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c2c08264-2296-4dea-afde-43557db5d793'	System	05 Oct 2020 19:19:50
User entered 'No (N)'	System	05 Oct 2020 19:19:50

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c2c08264-2296-4dea-afde-43557db5d793'	System	05 Oct 2020 19:19:50
User entered 'None (1)'	System	05 Oct 2020 19:19:50

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:47', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c2c08264-2296-4dea-afde-43557db5d793'	System	05 Oct 2020 19:19:50
User entered '05 Oct 2020 12:19'	System	05 Oct 2020 19:19:50

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 7'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2102a4ef-2b71-4411-910f-ac7b83016611'	System	06 Oct 2020 19:20:41
User entered 'None (1)'	System	06 Oct 2020 19:20:41

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:35', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2102a4ef-2b71-4411-910f-ac7b83016611'	System	06 Oct 2020 19:20:41
User entered 'No (N)'	System	06 Oct 2020 19:20:41

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2102a4ef-2b71-4411-910f-ac7b83016611'	System	06 Oct 2020 19:20:41
User entered 'No (N)'	System	06 Oct 2020 19:20:41

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:43', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2102a4ef-2b71-4411-910f-ac7b83016611'	System	06 Oct 2020 19:20:41
User entered 'None (1)'	System	06 Oct 2020 19:20:41

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:46', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2102a4ef-2b71-4411-910f-ac7b83016611'	System	06 Oct 2020 19:20:41
User entered '06 Oct 2020 12:15'	System	06 Oct 2020 19:20:41

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:44', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:56', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'None (0)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:05:59', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered 'No (N)'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T12:06:07', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '972b9869-a735-4443-b33a-243b4769d1aa'	System	30 Sep 2020 19:06:11
User entered '30 Sep 2020 12:06'	System	30 Sep 2020 19:06:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 14:11'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:23', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'None (0)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:30', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:33', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'None (0)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'None (0)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'None (0)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'None (0)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered 'No (N)'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-09-30T18:07:49', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f21f92fd-58b4-4dca-ac86-a96f9521625d'	System	01 Oct 2020 01:07:55
User entered '30 Sep 2020 18:07'	System	01 Oct 2020 01:07:55

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '30 Sep 2020 15:06'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 2'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:17', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'None (0)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:20', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'None (0)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:30', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'None (0)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'No interference with activity (1)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'None (0)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'None (0)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:52', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered 'No (N)'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-01T12:01:57', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '7d874831-9dbb-4d82-9175-2dd04a4ea30a'	System	01 Oct 2020 19:02:11
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 19:02:11

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 3'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'None (0)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'No interference with activity (1)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:22:59', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'No interference with activity (1)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:23:04', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'Some interference with activity (2)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:23:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'None (0)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:23:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'None (0)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:23:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered 'No (N)'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-02T12:23:20', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5b41e2f9-8bbd-474d-893e-89291d28d6d9'	System	02 Oct 2020 19:23:23
User entered '02 Oct 2020 12:23'	System	02 Oct 2020 19:23:23

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 4'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:03', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'None (0)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:06', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'None (0)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'None (0)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:12', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:14', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'None (0)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:17', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'None (0)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:20', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered 'No (N)'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-03T12:33:27', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd364dfb2-e34a-411e-9b5a-52feb743cba7'	System	03 Oct 2020 19:33:29
User entered '03 Oct 2020 12:33'	System	03 Oct 2020 19:33:29

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 5'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:07', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'None (0)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered 'No (N)'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-04T13:13:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a7d0bd3c-7e52-4b77-88dc-8278ee721501'	System	04 Oct 2020 20:13:24
User entered '04 Oct 2020 13:13'	System	04 Oct 2020 20:13:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 6'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'None (0)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:19:53', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'None (0)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'No interference with activity (1)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'Some interference with activity (2)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'None (0)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'None (0)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered 'No (N)'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-05T12:20:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fa414f6a-33a0-4820-9e22-2768c1bfe1a5'	System	05 Oct 2020 19:20:20
User entered '05 Oct 2020 12:20'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	30 Sep 2020 18:38:24
User entered 'Day 7'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'None (0)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:15:57', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'None (0)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'No interference with activity (1)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'No interference with activity (1)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'None (0)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'None (0)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered 'No (N)'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-06T12:16:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c1f0240b-605e-4e06-a4f7-ae62079f3fd4'	System	06 Oct 2020 19:20:52
User entered '06 Oct 2020 12:16'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 18:38:24

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	05 Oct 2020 19:20:20
User entered 'Day 8'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:00:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9c2f96cd-f17c-48ab-b2f2-e28421e7f42c'	System	07 Oct 2020 19:01:06
User entered 'None (0)'	System	07 Oct 2020 19:01:06

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:00:58', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9c2f96cd-f17c-48ab-b2f2-e28421e7f42c'	System	07 Oct 2020 19:01:06
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 19:01:06

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	05 Oct 2020 19:20:20
User entered 'Day 8'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:01:04', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '995b84a1-a483-4507-9a79-f10226efe468'	System	07 Oct 2020 19:01:12
User entered 'No interference with activity (1)'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:01:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '995b84a1-a483-4507-9a79-f10226efe468'	System	07 Oct 2020 19:01:12
User entered '07 Oct 2020 12:01'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	06 Oct 2020 19:20:52
User entered 'Day 9'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-08T12:00:40', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '79ade51e-10f9-478e-93a5-6bd88f0df03d'	System	08 Oct 2020 19:00:48
User entered 'No interference with activity (1)'	System	08 Oct 2020 19:00:48

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-08T12:00:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '79ade51e-10f9-478e-93a5-6bd88f0df03d'	System	08 Oct 2020 19:00:48
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 19:00:48

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	07 Oct 2020 19:01:12
User entered 'Day 10'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-09T13:09:23', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '8f71960a-fb56-451e-bddc-ddb8d4f0efb1'	System	09 Oct 2020 20:09:34
User entered 'None (0)'	System	09 Oct 2020 20:09:34

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-09T13:09:29', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '8f71960a-fb56-451e-bddc-ddb8d4f0efb1'	System	09 Oct 2020 20:09:34
User entered '09 Oct 2020 13:09'	System	09 Oct 2020 20:09:34

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	05 Oct 2020 19:20:20
User entered 'Day 8'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:01:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '76766d17-b2d7-4de4-82b4-484514e54e47'	System	07 Oct 2020 19:01:21
User entered 'No (N)'	System	07 Oct 2020 19:01:21

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-07T12:01:20', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '76766d17-b2d7-4de4-82b4-484514e54e47'	System	07 Oct 2020 19:01:21
User entered '07 Oct 2020 12:01'	System	07 Oct 2020 19:01:21

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:20:20

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
DataPoint Activated.	System	07 Oct 2020 19:01:12
DataPoint Inactivated.	System	07 Oct 2020 19:01:06
Data entry locked.	System	06 Oct 2020 19:20:52
User entered 'Day 9'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-08T12:00:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '6083e012-bac5-4339-ae33-4b61caab178b'	System	08 Oct 2020 19:00:56
User entered 'No (N)'	System	08 Oct 2020 19:00:56
DataPoint Activated.	System	07 Oct 2020 19:01:12
DataPoint Inactivated.	System	07 Oct 2020 19:01:06

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-08T12:00:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '6083e012-bac5-4339-ae33-4b61caab178b'	System	08 Oct 2020 19:00:56
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 19:00:56
DataPoint Activated.	System	07 Oct 2020 19:01:12
DataPoint Inactivated.	System	07 Oct 2020 19:01:06

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
DataPoint Activated.	System	07 Oct 2020 19:01:12
DataPoint Inactivated.	System	07 Oct 2020 19:01:06
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
DataPoint Activated.	System	07 Oct 2020 19:01:12
DataPoint Inactivated.	System	07 Oct 2020 19:01:06
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:20:52

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	07 Oct 2020 19:01:12
User entered 'Day 10'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-09T13:09:35', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fed6df51-96b1-41e7-8f87-4106f40e1a81'	System	09 Oct 2020 20:09:43
User entered 'No (N)'	System	09 Oct 2020 20:09:43

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-10-09T13:09:40', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fed6df51-96b1-41e7-8f87-4106f40e1a81'	System	09 Oct 2020 20:09:43
User entered '09 Oct 2020 13:09'	System	09 Oct 2020 20:09:43

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:01:12

US3792080

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:01:12

US3792080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	07 Oct 2020 18:15:27
	(b) (4)	

US3792080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '7 Oct 2020'	Ann Marie Milliken (b) (4)	07 Oct 2020 18:15:27
	(b) (4)	

US3792080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	07 Oct 2020 18:15:27
	(b) (4)	

US3792080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Ann Marie Milliken (b) (4)	07 Oct 2020 18:15:27
	(b) (4)	

US3792080

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	07 Oct 2020 18:15:32
	(b) (4)	

US3792080

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'I'	System	07 Oct 2020 18:15:32

US3792080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken	14 Oct 2020 21:53:20
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '14 Oct 2020'	Ann Marie Milliken (b) (4)	14 Oct 2020 21:53:20
	(b) (4)	

US3792080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken	14 Oct 2020 21:53:20
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Ann Marie Milliken	14 Oct 2020 21:53:20
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken	14 Oct 2020 21:53:24
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:00
User entered 'I'	System	14 Oct 2020 21:53:24

US3792080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	21 Oct 2020 19:51:01

US3792080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:19
User entered '21 Oct 2020'	Ann Marie Milliken (b) (4) (b) (4)	21 Oct 2020 19:51:01

US3792080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:19
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4) (b) (4)	21 Oct 2020 19:51:01

US3792080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:19
User entered empty.	Ann Marie Milliken (b) (4) (b) (4)	21 Oct 2020 19:51:01

US3792080

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:24
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	21 Oct 2020 19:51:06

US3792080

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	21 Oct 2020 19:51:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:58
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:01:29

US3792080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:58
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:01:29

US3792080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[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 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:29:58
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:01:29

US3792080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'VISIT2'	System	04 Nov 2020 17:01:29

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '09:33'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '4 Nov 2020 09:33'	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '97.7' F	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '66'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'bpm'	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '14'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'breaths/min'	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '115'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '81'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '10:36' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '4 Nov 2020 10:36'	System	04 Nov 2020 18:10:53
User entered empty.	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '98.3' F reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 18:10:53
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:02:40
	(b) (4)	

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '60' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'bpm'	System	04 Nov 2020 18:10:53
User entered empty.	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'breaths/min'	System	04 Nov 2020 18:10:53
User entered empty.	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '109' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	04 Nov 2020 18:10:53
User entered empty.	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:16
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 18:10:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Nov 2020 18:10:53
User entered '74' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 18:10:53
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 17:02:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	04 Nov 2020 18:10:53
User entered empty.	System	04 Nov 2020 17:02:40

US3792080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:48
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:53

US3792080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:31:48
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:02:53

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:14
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:18
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:19
User entered 'Urine (URINE)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User closed query 'Please indicate result of the pregnancy test in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:59:31
Query 'Please indicate result of the pregnancy test in source.' answered with 'source updated ' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 15:34:25
DataPoint Verified.	(b) (4), (b) (6)	15 Jan 2021 21:55:56
User opened query 'Please indicate result of the pregnancy test in source.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 16:37:44
User entered 'Negative (NEGATIVE)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:22
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered empty.	System	04 Nov 2020 17:03:17

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'MRNA-1273 OR PLACEBO'	System	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered '10:02'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '4 Nov 2020 10:02'	System	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:40:29
User entered 'ONCE'	System	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'INTRAMUSCULAR'	System	04 Nov 2020 17:15:38

US3792080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:26
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:04:47

US3792080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:26
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:04:47

US3792080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:26
User entered '09:38'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:04:47

US3792080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '4 Nov 2020 09:38'	System	04 Nov 2020 17:04:47

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:52
User entered '4 Nov 2020'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:52
User entered '09:43'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '4 Nov 2020 09:43'	System	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:52
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:52
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered empty.	System	04 Nov 2020 17:05:06

US3792080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:39:57
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:11

US3792080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	04 Nov 2020 17:05:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fe9d9557-bca3-4cbf-9017-1024de2fee50'	System	04 Nov 2020 17:37:41
User entered 'Yes (Y)'	System	04 Nov 2020 17:37:41

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fe9d9557-bca3-4cbf-9017-1024de2fee50'	System	04 Nov 2020 17:37:41
User entered '98.3'	System	04 Nov 2020 17:37:41

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:24', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fe9d9557-bca3-4cbf-9017-1024de2fee50'	System	04 Nov 2020 17:37:41
User entered 'No (N)'	System	04 Nov 2020 17:37:41

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:33', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'fe9d9557-bca3-4cbf-9017-1024de2fee50'	System	04 Nov 2020 17:37:41
User entered '04 Nov 2020 10:37'	System	04 Nov 2020 17:37:41

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 10:22'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 12:52'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 13:47'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 2'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '77e9a87c-8a76-48c6-ab54-f549e32f69f0'	System	06 Nov 2020 00:36:30
User entered 'Yes (Y)'	System	06 Nov 2020 00:36:30

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '77e9a87c-8a76-48c6-ab54-f549e32f69f0'	System	06 Nov 2020 00:36:30
User entered '98.3'	System	06 Nov 2020 00:36:30

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:14', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '77e9a87c-8a76-48c6-ab54-f549e32f69f0'	System	06 Nov 2020 00:36:30
User entered 'No (N)'	System	06 Nov 2020 00:36:30

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:27', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '77e9a87c-8a76-48c6-ab54-f549e32f69f0'	System	06 Nov 2020 00:36:30
User entered '05 Nov 2020 17:36'	System	06 Nov 2020 00:36:30

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 3'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:14:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f74b2be0-00c6-42e3-b9d3-3323c85bd433'	System	06 Nov 2020 19:14:20
User entered 'Yes (Y)'	System	06 Nov 2020 19:14:20

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:14:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f74b2be0-00c6-42e3-b9d3-3323c85bd433'	System	06 Nov 2020 19:14:20
User entered '99.6'	System	06 Nov 2020 19:14:20

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:14:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f74b2be0-00c6-42e3-b9d3-3323c85bd433'	System	06 Nov 2020 19:14:20
User entered 'No (N)'	System	06 Nov 2020 19:14:20

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:14:17', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'f74b2be0-00c6-42e3-b9d3-3323c85bd433'	System	06 Nov 2020 19:14:20
User entered '06 Nov 2020 12:14'	System	06 Nov 2020 19:14:20

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 4'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:07:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c8ee495f-cde2-40fb-b402-608353521ec6'	System	08 Nov 2020 00:08:07
User entered 'Yes (Y)'	System	08 Nov 2020 00:08:07

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:07:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c8ee495f-cde2-40fb-b402-608353521ec6'	System	08 Nov 2020 00:08:07
User entered '98.6'	System	08 Nov 2020 00:08:07

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:07:57', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c8ee495f-cde2-40fb-b402-608353521ec6'	System	08 Nov 2020 00:08:07
User entered 'No (N)'	System	08 Nov 2020 00:08:07

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c8ee495f-cde2-40fb-b402-608353521ec6'	System	08 Nov 2020 00:08:07
User entered '07 Nov 2020 17:08'	System	08 Nov 2020 00:08:07

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 5'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:20:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3e1330c3-da9f-4bd0-907f-44696bd90f72'	System	08 Nov 2020 20:21:11
User entered 'Yes (Y)'	System	08 Nov 2020 20:21:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3e1330c3-da9f-4bd0-907f-44696bd90f72'	System	08 Nov 2020 20:21:11
User entered '98.7'	System	08 Nov 2020 20:21:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3e1330c3-da9f-4bd0-907f-44696bd90f72'	System	08 Nov 2020 20:21:11
User entered 'No (N)'	System	08 Nov 2020 20:21:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:10', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3e1330c3-da9f-4bd0-907f-44696bd90f72'	System	08 Nov 2020 20:21:11
User entered '08 Nov 2020 13:21'	System	08 Nov 2020 20:21:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 6'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3031716-2204-4edf-93d1-d61782c9b497'	System	10 Nov 2020 02:04:19
User entered 'Yes (Y)'	System	10 Nov 2020 02:04:19

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:06', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3031716-2204-4edf-93d1-d61782c9b497'	System	10 Nov 2020 02:04:19
User entered '98.1'	System	10 Nov 2020 02:04:19

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3031716-2204-4edf-93d1-d61782c9b497'	System	10 Nov 2020 02:04:19
User entered 'No (N)'	System	10 Nov 2020 02:04:19

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3031716-2204-4edf-93d1-d61782c9b497'	System	10 Nov 2020 02:04:19
User entered '09 Nov 2020 19:04'	System	10 Nov 2020 02:04:19

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 7'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:35:55', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '626237a1-cd58-4dca-a1e4-a445ba12a279'	System	11 Nov 2020 00:36:11
User entered 'Yes (Y)'	System	11 Nov 2020 00:36:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:01', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '626237a1-cd58-4dca-a1e4-a445ba12a279'	System	11 Nov 2020 00:36:11
User entered '98.3'	System	11 Nov 2020 00:36:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:04', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '626237a1-cd58-4dca-a1e4-a445ba12a279'	System	11 Nov 2020 00:36:11
User entered 'No (N)'	System	11 Nov 2020 00:36:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '626237a1-cd58-4dca-a1e4-a445ba12a279'	System	11 Nov 2020 00:36:11
User entered '10 Nov 2020 17:36'	System	11 Nov 2020 00:36:11

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'bb4f658b-1325-4859-8d2e-baf9757f7163'	System	04 Nov 2020 17:38:27
User entered 'None (1)'	System	04 Nov 2020 17:38:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:37:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'bb4f658b-1325-4859-8d2e-baf9757f7163'	System	04 Nov 2020 17:38:27
User entered 'No (N)'	System	04 Nov 2020 17:38:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:06', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'bb4f658b-1325-4859-8d2e-baf9757f7163'	System	04 Nov 2020 17:38:27
User entered 'No (N)'	System	04 Nov 2020 17:38:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'bb4f658b-1325-4859-8d2e-baf9757f7163'	System	04 Nov 2020 17:38:27
User entered 'None (1)'	System	04 Nov 2020 17:38:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'bb4f658b-1325-4859-8d2e-baf9757f7163'	System	04 Nov 2020 17:38:27
User entered '04 Nov 2020 10:38'	System	04 Nov 2020 17:38:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 10:22'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 12:52'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 13:47'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 2'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9ef2eae3-fe61-4715-b6ce-eb9f7783e672'	System	06 Nov 2020 00:36:53
User entered 'None (1)'	System	06 Nov 2020 00:36:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:34', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9ef2eae3-fe61-4715-b6ce-eb9f7783e672'	System	06 Nov 2020 00:36:53
User entered 'No (N)'	System	06 Nov 2020 00:36:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9ef2eae3-fe61-4715-b6ce-eb9f7783e672'	System	06 Nov 2020 00:36:53
User entered 'No (N)'	System	06 Nov 2020 00:36:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:45', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9ef2eae3-fe61-4715-b6ce-eb9f7783e672'	System	06 Nov 2020 00:36:53
User entered 'None (1)'	System	06 Nov 2020 00:36:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:36:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9ef2eae3-fe61-4715-b6ce-eb9f7783e672'	System	06 Nov 2020 00:36:53
User entered '05 Nov 2020 17:36'	System	06 Nov 2020 00:36:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 3'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c114e210-5e9e-47ae-825a-c7bd60b10a5e'	System	06 Nov 2020 19:12:31
User entered 'None (1)'	System	06 Nov 2020 19:12:31

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c114e210-5e9e-47ae-825a-c7bd60b10a5e'	System	06 Nov 2020 19:12:31
User entered 'No (N)'	System	06 Nov 2020 19:12:31

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c114e210-5e9e-47ae-825a-c7bd60b10a5e'	System	06 Nov 2020 19:12:31
User entered 'No (N)'	System	06 Nov 2020 19:12:31

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c114e210-5e9e-47ae-825a-c7bd60b10a5e'	System	06 Nov 2020 19:12:31
User entered 'None (1)'	System	06 Nov 2020 19:12:31

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:28', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'c114e210-5e9e-47ae-825a-c7bd60b10a5e'	System	06 Nov 2020 19:12:31
User entered '06 Nov 2020 12:12'	System	06 Nov 2020 19:12:31

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 4'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:07', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '67213e54-2609-4768-9bb6-2f324d094e52'	System	08 Nov 2020 00:08:27
User entered 'None (1)'	System	08 Nov 2020 00:08:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '67213e54-2609-4768-9bb6-2f324d094e52'	System	08 Nov 2020 00:08:27
User entered 'No (N)'	System	08 Nov 2020 00:08:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:19', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '67213e54-2609-4768-9bb6-2f324d094e52'	System	08 Nov 2020 00:08:27
User entered 'No (N)'	System	08 Nov 2020 00:08:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:22', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '67213e54-2609-4768-9bb6-2f324d094e52'	System	08 Nov 2020 00:08:27
User entered 'None (1)'	System	08 Nov 2020 00:08:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:25', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '67213e54-2609-4768-9bb6-2f324d094e52'	System	08 Nov 2020 00:08:27
User entered '07 Nov 2020 17:08'	System	08 Nov 2020 00:08:27

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 5'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:14', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd18ae2b5-3d16-4942-a536-a7704915c3d8'	System	08 Nov 2020 20:21:30
User entered 'None (1)'	System	08 Nov 2020 20:21:30

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd18ae2b5-3d16-4942-a536-a7704915c3d8'	System	08 Nov 2020 20:21:30
User entered 'No (N)'	System	08 Nov 2020 20:21:30

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:22', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd18ae2b5-3d16-4942-a536-a7704915c3d8'	System	08 Nov 2020 20:21:30
User entered 'No (N)'	System	08 Nov 2020 20:21:30

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:25', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd18ae2b5-3d16-4942-a536-a7704915c3d8'	System	08 Nov 2020 20:21:30
User entered 'None (1)'	System	08 Nov 2020 20:21:30

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:28', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'd18ae2b5-3d16-4942-a536-a7704915c3d8'	System	08 Nov 2020 20:21:30
User entered '08 Nov 2020 13:21'	System	08 Nov 2020 20:21:30

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 6'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:23', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ca07aff2-f14a-4ee5-ac48-3722d684a794'	System	10 Nov 2020 02:04:53
User entered 'None (1)'	System	10 Nov 2020 02:04:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:28', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ca07aff2-f14a-4ee5-ac48-3722d684a794'	System	10 Nov 2020 02:04:53
User entered 'No (N)'	System	10 Nov 2020 02:04:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ca07aff2-f14a-4ee5-ac48-3722d684a794'	System	10 Nov 2020 02:04:53
User entered 'No (N)'	System	10 Nov 2020 02:04:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ca07aff2-f14a-4ee5-ac48-3722d684a794'	System	10 Nov 2020 02:04:53
User entered 'None (1)'	System	10 Nov 2020 02:04:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:49', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ca07aff2-f14a-4ee5-ac48-3722d684a794'	System	10 Nov 2020 02:04:53
User entered '09 Nov 2020 19:04'	System	10 Nov 2020 02:04:53

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 7'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:14', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '45a4c3d3-84be-4b99-a476-1242690d1902'	System	11 Nov 2020 00:36:34
User entered 'None (1)'	System	11 Nov 2020 00:36:34

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '45a4c3d3-84be-4b99-a476-1242690d1902'	System	11 Nov 2020 00:36:34
User entered 'No (N)'	System	11 Nov 2020 00:36:34

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:19', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '45a4c3d3-84be-4b99-a476-1242690d1902'	System	11 Nov 2020 00:36:34
User entered 'No (N)'	System	11 Nov 2020 00:36:34

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:27', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '45a4c3d3-84be-4b99-a476-1242690d1902'	System	11 Nov 2020 00:36:34
User entered 'None (1)'	System	11 Nov 2020 00:36:34

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '45a4c3d3-84be-4b99-a476-1242690d1902'	System	11 Nov 2020 00:36:34
User entered '10 Nov 2020 17:36'	System	11 Nov 2020 00:36:34

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:29', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:34', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'None (0)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:47', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered 'No (N)'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-04T10:38:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '2e845324-b578-4f24-8e4b-5106d72cd211'	System	04 Nov 2020 17:38:54
User entered '04 Nov 2020 10:38'	System	04 Nov 2020 17:38:54

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 10:22'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 12:52'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '04 Nov 2020 13:47'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 2'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:04', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:07', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:09', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:13', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'None (0)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered 'No (N)'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-05T17:37:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '3c882efd-efb0-4e71-b5a8-97d45e501f89'	System	06 Nov 2020 00:37:27
User entered '05 Nov 2020 17:37'	System	06 Nov 2020 00:37:27

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 3'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:34', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:40', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:44', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'None (0)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:47', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered 'No (N)'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-06T12:12:52', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '9f1252c8-077c-4a4b-b3b5-e22be4f24c63'	System	06 Nov 2020 19:12:55
User entered '06 Nov 2020 12:12'	System	06 Nov 2020 19:12:55

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 4'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:29', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:31', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:34', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:39', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:41', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'None (0)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:44', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered 'No (N)'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-07T17:08:49', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ac1ed368-b97a-459f-9caf-3d05c4368692'	System	08 Nov 2020 00:08:51
User entered '07 Nov 2020 17:08'	System	08 Nov 2020 00:08:51

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 5'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:35', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:37', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:39', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:41', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:43', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'None (0)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:46', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered 'No (N)'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-08T13:21:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'da5885b2-bfdc-42e8-87d5-48be690cc874'	System	08 Nov 2020 20:21:53
User entered '08 Nov 2020 13:21'	System	08 Nov 2020 20:21:53

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 6'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:04:55', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:23', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:26', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:28', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'None (0)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered 'No (N)'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-09T19:05:46', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5ac48132-aa15-4e2d-975a-d5cad31229db'	System	10 Nov 2020 02:05:49
User entered '09 Nov 2020 19:05'	System	10 Nov 2020 02:05:49

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
Data entry locked.	System	04 Nov 2020 17:15:38
User entered 'Day 7'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:38', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:42', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:44', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:46', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:48', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'None (0)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

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 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered 'No (N)'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-10T17:36:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1fdbfe0d-7983-47c8-b70e-ffe56d3e424c'	System	11 Nov 2020 00:36:56
User entered '10 Nov 2020 17:36'	System	11 Nov 2020 00:36:56

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 17:15:38

US3792080

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:37:43
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 17:15:38

US3792080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:23:53
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	11 Nov 2020 19:02:02

US3792080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:23:53
User entered '11 Nov 2020'	Ann Marie Milliken (b) (4) (b) (4)	11 Nov 2020 19:02:02

US3792080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:23:53
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4) (b) (4)	11 Nov 2020 19:02:02

US3792080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:23:53
User entered empty.	Ann Marie Milliken (b) (4) (b) (4)	11 Nov 2020 19:02:02

US3792080

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:25:30
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	11 Nov 2020 19:02:08

US3792080

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	11 Nov 2020 19:02:08

US3792080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:26:20
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 17:13:34

US3792080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:26:20
User entered '18 Nov 2020'	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 17:13:34

US3792080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:26:20
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 17:13:34

US3792080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:26:20
User entered empty.	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 17:13:34

US3792080

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:26:28
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4) (b) (4)	18 Nov 2020 17:13:40

US3792080

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	18 Nov 2020 17:13:40

US3792080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:27:20
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:55:35

US3792080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:27:20
User entered '25 Nov 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:55:35

US3792080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:27:20
User entered 'Contact Not Made (CONTACT NOT MADE)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:55:35

US3792080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:27:20
User entered 'left a voicemail asked her to call me back'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:55:35

US3792080

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Dec 2020 19:10:13

US3792080

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	09 Dec 2020 19:10:13

US3792080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:44:14
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:10:28

US3792080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:44:14
User entered '9 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:10:28

US3792080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[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 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:44:14
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:10:28

US3792080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'VISIT3'	System	09 Dec 2020 19:10:28

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '9 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '11:01'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '9 Dec 2020 11:01'	System	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '98.5' F	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '62'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'bpm'	System	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '16'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'breaths/min'	System	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '113'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:30
User entered '75'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'mmHg'	System	09 Dec 2020 19:11:09

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57

US3792080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57

US3792080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:55
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:17

US3792080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:55
User entered '9 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:17

US3792080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:59:48
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:34

US3792080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:59:48
User entered '9 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:34

US3792080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:59:48
User entered '11:09'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:34

US3792080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered '9 Dec 2020 11:09'	System	09 Dec 2020 19:11:34

US3792080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:00:27
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:11:38

US3792080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	09 Dec 2020 19:11:38

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2020-11-27T00:01:32', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '8409373d-85d0-432f-9e99-e130cd3446f5'	System	27 Nov 2020 07:03:21
User entered 'No (N)'	System	27 Nov 2020 07:03:21

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2020-11-27T00:03:08', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '8409373d-85d0-432f-9e99-e130cd3446f5'	System	27 Nov 2020 07:03:21
User entered 'No (N)'	System	27 Nov 2020 07:03:21

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-11-27T00:03:16', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '8409373d-85d0-432f-9e99-e130cd3446f5'	System	27 Nov 2020 07:03:21
User entered '27 Nov 2020 00:03:16'	System	27 Nov 2020 07:03:21

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2020-12-04T00:01:19', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '517395f8-b1f7-4384-8e15-d97eaf9a8862'	System	04 Dec 2020 07:01:42
User entered 'No (N)'	System	04 Dec 2020 07:01:42

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2020-12-04T00:01:24', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '517395f8-b1f7-4384-8e15-d97eaf9a8862'	System	04 Dec 2020 07:01:42
User entered 'No (N)'	System	04 Dec 2020 07:01:42

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-12-04T00:01:36', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '517395f8-b1f7-4384-8e15-d97eaf9a8862'	System	04 Dec 2020 07:01:42
User entered '04 Dec 2020 00:01:36'	System	04 Dec 2020 07:01:42

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2020-12-11T03:49:39', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a605baf8-c306-4e88-9244-62f922d6428f' User entered 'No (N)'	System	11 Dec 2020 10:49:53

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2020-12-11T03:49:44', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a605baf8-c306-4e88-9244-62f922d6428f'	System	11 Dec 2020 10:49:53
User entered 'No (N)'	System	11 Dec 2020 10:49:53

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-12-11T03:49:50', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a605baf8-c306-4e88-9244-62f922d6428f' User entered '11 Dec 2020 03:49:50'	System	11 Dec 2020 10:49:53
	System	11 Dec 2020 10:49:53

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2020-12-22T16:46:11', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4e07b450-4c5b-4576-a913-efc861b48b87'	System	22 Dec 2020 23:46:27
User entered 'No (N)'	System	22 Dec 2020 23:46:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2020-12-22T16:46:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4e07b450-4c5b-4576-a913-efc861b48b87'	System	22 Dec 2020 23:46:27
User entered 'No (N)'	System	22 Dec 2020 23:46:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2020-12-22T16:46:22', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4e07b450-4c5b-4576-a913-efc861b48b87'	System	22 Dec 2020 23:46:27
User entered '22 Dec 2020 16:46:22'	System	22 Dec 2020 23:46:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-01-01T00:01:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3f0921d-2b92-49e4-807a-6173d4b9874f'	System	01 Jan 2021 07:01:27
User entered 'No (N)'	System	01 Jan 2021 07:01:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-01-01T00:01:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3f0921d-2b92-49e4-807a-6173d4b9874f'	System	01 Jan 2021 07:01:27
User entered 'No (N)'	System	01 Jan 2021 07:01:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-01-01T00:01:24', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b3f0921d-2b92-49e4-807a-6173d4b9874f' User entered '01 Jan 2021 00:01:24'	System	01 Jan 2021 07:01:27
	System	01 Jan 2021 07:01:27

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-01-08T00:57:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b6227a9b-87b9-44ac-a0b9-d27a4b199216'	System	08 Jan 2021 07:57:09
User entered 'No (N)'	System	08 Jan 2021 07:57:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-01-08T00:57:03', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b6227a9b-87b9-44ac-a0b9-d27a4b199216'	System	08 Jan 2021 07:57:09
User entered 'No (N)'	System	08 Jan 2021 07:57:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-01-08T00:57:06', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b6227a9b-87b9-44ac-a0b9-d27a4b199216'	System	08 Jan 2021 07:57:09
User entered '08 Jan 2021 00:57:06'	System	08 Jan 2021 07:57:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-01-22T00:06:51', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a71f5933-e20e-4fce-8c3e-99efd297d733'	System	22 Jan 2021 07:07:01
User entered 'No (N)'	System	22 Jan 2021 07:07:01

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-01-22T00:06:54', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a71f5933-e20e-4fce-8c3e-99efd297d733'	System	22 Jan 2021 07:07:01
User entered 'No (N)'	System	22 Jan 2021 07:07:01

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-01-22T00:06:57', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a71f5933-e20e-4fce-8c3e-99efd297d733'	System	22 Jan 2021 07:07:01
User entered '22 Jan 2021 00:06:57'	System	22 Jan 2021 07:07:01

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-01-30T03:04:59', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '121fba6e-bccd-4037-8d49-541b05a2a2d5'	System	30 Jan 2021 10:05:09
User entered 'No (N)'	System	30 Jan 2021 10:05:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-01-30T03:05:02', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '121fba6e-bccd-4037-8d49-541b05a2a2d5'	System	30 Jan 2021 10:05:09
User entered 'No (N)'	System	30 Jan 2021 10:05:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-01-30T03:05:05', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '121fba6e-bccd-4037-8d49-541b05a2a2d5'	System	30 Jan 2021 10:05:09
User entered '30 Jan 2021 03:05:05'	System	30 Jan 2021 10:05:09

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-02-14T01:21:23', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '90cc1a73-822f-4599-8b17-966075513706'	System	14 Feb 2021 08:21:41
User entered 'No (N)'	System	14 Feb 2021 08:21:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-02-14T01:21:25', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '90cc1a73-822f-4599-8b17-966075513706'	System	14 Feb 2021 08:21:41
User entered 'No (N)'	System	14 Feb 2021 08:21:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-02-14T01:21:31', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '90cc1a73-822f-4599-8b17-966075513706'	System	14 Feb 2021 08:21:41
User entered '14 Feb 2021 01:21:31'	System	14 Feb 2021 08:21:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-02-20T19:18:15', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b9637493-467b-447e-bf1d-6738d613ea30'	System	21 Feb 2021 02:20:39
User entered 'No (N)'	System	21 Feb 2021 02:20:39

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-02-20T19:18:18', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b9637493-467b-447e-bf1d-6738d613ea30'	System	21 Feb 2021 02:20:39
User entered 'No (N)'	System	21 Feb 2021 02:20:39

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-02-20T19:18:21', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'b9637493-467b-447e-bf1d-6738d613ea30'	System	21 Feb 2021 02:20:39
User entered '20 Feb 2021 19:18:21'	System	21 Feb 2021 02:20:39

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-02-26T08:46:49-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '523e6a9d-55de-4a89-9ba3-cb82787f2063'	System	26 Feb 2021 15:47:00
User entered 'No (N)'	System	26 Feb 2021 15:47:00

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-02-26T08:46:54-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '523e6a9d-55de-4a89-9ba3-cb82787f2063'	System	26 Feb 2021 15:47:00
User entered 'No (N)'	System	26 Feb 2021 15:47:00

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-02-26T08:46:58-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '523e6a9d-55de-4a89-9ba3-cb82787f2063'	System	26 Feb 2021 15:47:00
User entered '26 Feb 2021 08:46:58'	System	26 Feb 2021 15:47:00

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-03-07T21:07:32-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1f605c9d-3a43-4342-bea4-c09f1edd969b'	System	08 Mar 2021 04:07:45
User entered 'No (N)'	System	08 Mar 2021 04:07:45

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-03-07T21:07:35-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1f605c9d-3a43-4342-bea4-c09f1edd969b'	System	08 Mar 2021 04:07:45
User entered 'No (N)'	System	08 Mar 2021 04:07:45

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-07T21:07:38-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '1f605c9d-3a43-4342-bea4-c09f1edd969b'	System	08 Mar 2021 04:07:45
User entered '07 Mar 2021 21:07:38'	System	08 Mar 2021 04:07:45

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-03-12T00:01:17-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4eac0d4a-b7c6-495e-969f-08622e165ae7'	System	12 Mar 2021 07:01:31
User entered 'No (N)'	System	12 Mar 2021 07:01:31

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-03-12T00:01:21-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4eac0d4a-b7c6-495e-969f-08622e165ae7'	System	12 Mar 2021 07:01:31
User entered 'No (N)'	System	12 Mar 2021 07:01:31

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-12T00:01:25-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '4eac0d4a-b7c6-495e-969f-08622e165ae7'	System	12 Mar 2021 07:01:31
User entered '12 Mar 2021 00:01:25'	System	12 Mar 2021 07:01:31

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-03-19T08:26:49-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '776f9eee-fa22-4ab1-9606-7f45ee848878'	System	19 Mar 2021 15:27:05
User entered 'No (N)'	System	19 Mar 2021 15:27:05

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-03-19T08:26:53-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '776f9eee-fa22-4ab1-9606-7f45ee848878'	System	19 Mar 2021 15:27:05
User entered 'No (N)'	System	19 Mar 2021 15:27:05

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-19T08:26:55-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '776f9eee-fa22-4ab1-9606-7f45ee848878' User entered '19 Mar 2021 08:26:55'	System	19 Mar 2021 15:27:05
	System	19 Mar 2021 15:27:05

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-03-29T09:21:19-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a0b9af8f-9f28-4297-bca8-f9a4fa923430'	System	29 Mar 2021 16:21:35
User entered 'No (N)'	System	29 Mar 2021 16:21:35

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-03-29T09:21:24-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a0b9af8f-9f28-4297-bca8-f9a4fa923430'	System	29 Mar 2021 16:21:35
User entered 'No (N)'	System	29 Mar 2021 16:21:35

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-29T09:21:27-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a0b9af8f-9f28-4297-bca8-f9a4fa923430' User entered '29 Mar 2021 09:21:27'	System	29 Mar 2021 16:21:35
	System	29 Mar 2021 16:21:35

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-04-03T17:40:28-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5c661639-59c5-41b9-bac6-6b58aa716162'	System	04 Apr 2021 00:40:37
User entered 'No (N)'	System	04 Apr 2021 00:40:37

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-04-03T17:40:31-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5c661639-59c5-41b9-bac6-6b58aa716162'	System	04 Apr 2021 00:40:37
User entered 'No (N)'	System	04 Apr 2021 00:40:37

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-04-03T17:40:34-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '5c661639-59c5-41b9-bac6-6b58aa716162'	System	04 Apr 2021 00:40:37
User entered '03 Apr 2021 17:40:34'	System	04 Apr 2021 00:40:37

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-04-09T18:19:33-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a2093653-8153-41eb-ba19-a30b4a3d0770'	System	10 Apr 2021 01:19:41
User entered 'No (N)'	System	10 Apr 2021 01:19:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-04-09T18:19:35-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a2093653-8153-41eb-ba19-a30b4a3d0770'	System	10 Apr 2021 01:19:41
User entered 'No (N)'	System	10 Apr 2021 01:19:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-04-09T18:19:38-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'a2093653-8153-41eb-ba19-a30b4a3d0770'	System	10 Apr 2021 01:19:41
User entered '09 Apr 2021 18:19:38'	System	10 Apr 2021 01:19:41

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-04-23T00:57:08-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '0ebc8836-a764-4b6a-a8ce-896d5822a64a' User entered 'No (N)'	System	23 Apr 2021 07:57:19
	System	23 Apr 2021 07:57:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-04-23T00:57:12-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '0ebc8836-a764-4b6a-a8ce-896d5822a64a'	System	23 Apr 2021 07:57:19
User entered 'No (N)'	System	23 Apr 2021 07:57:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-04-23T00:57:16-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '0ebc8836-a764-4b6a-a8ce-896d5822a64a'	System	23 Apr 2021 07:57:19
User entered '23 Apr 2021 00:57:16'	System	23 Apr 2021 07:57:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[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 (ca3d3675ef49986b)', Time: '2021-04-30T00:14:54-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ae08b5d0-fd3a-4c70-8124-5ccbf4b32ac5'	System	30 Apr 2021 07:15:06
User entered 'No (N)'	System	30 Apr 2021 07:15:06

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Have you been exposed to someone with 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 (ca3d3675ef49986b)', Time: '2021-04-30T00:14:57-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ae08b5d0-fd3a-4c70-8124-5ccbf4b32ac5'	System	30 Apr 2021 07:15:06
User entered 'No (N)'	System	30 Apr 2021 07:15:06

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-04-30T00:14:59-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: 'ae08b5d0-fd3a-4c70-8124-5ccbf4b32ac5'	System	30 Apr 2021 07:15:06
User entered '30 Apr 2021 00:14:59'	System	30 Apr 2021 07:15:06

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:21:19

US3792080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:21:19
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:21:19

US3792080

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:49:54

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)	30 Apr 2021 22:02:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-01T10:40:35-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '73ca9211-0557-4913-94b2-516bc0c72726'	System	01 Mar 2021 17:41:07
User entered 'No (N)'	System	01 Mar 2021 17:41:07

US3792080

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:49:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:02:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ca3d3675ef49986b)', Time: '2021-03-01T10:40:39-07:00', User OID: 'PatientReportedOutcome (US3792080)', ODM File OID: '73ca9211-0557-4913-94b2-516bc0c72726'	System	01 Mar 2021 17:41:07
User entered '01 Mar 2021 10:40:39'	System	01 Mar 2021 17:41:07

US3792080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4) (b) (4)	31 Dec 2020 15:55:59

US3792080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered '30 Dec 2020'	Ann Marie Milliken	31 Dec 2020 15:55:59
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	31 Dec 2020 15:55:59
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered empty.	(b) (4)	31 Dec 2020 15:55:59
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4) (b) (4)	31 Dec 2020 15:56:05

US3792080

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:57
User entered 'I'	System	31 Dec 2020 15:56:05

US3792080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken	05 Feb 2021 21:46:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '5 Feb 2021'	Ann Marie Milliken	05 Feb 2021 21:46:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken	05 Feb 2021 21:46:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Ann Marie Milliken	05 Feb 2021 21:46:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Ann Marie Milliken	05 Feb 2021 21:46:11
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User entered 'I'	System	05 Feb 2021 21:46:11

US3792080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 18:47:57
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '5 Mar 2021'	Ann Marie Milliken	05 Mar 2021 18:47:57
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken	05 Mar 2021 18:47:57
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	Ann Marie Milliken	05 Mar 2021 18:47:57
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:48:02
	(b) (4)	

US3792080

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:27
User entered 'I'	System	05 Mar 2021 18:48:02

US3792080

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	02 Apr 2021 21:46:21
	(b) (4)	

US3792080

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered '2 Apr 2021'	Ann Marie Milliken	02 Apr 2021 21:46:21
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Ann Marie Milliken	02 Apr 2021 21:46:21
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered empty.	(b) (4)	
	Ann Marie Milliken	02 Apr 2021 21:46:21
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered 'Yes (Y)'	(b) (4)	02 Apr 2021 21:46:27
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:35
User entered 'I'	System	02 Apr 2021 21:46:27

US3792080

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:36:44

US3792080

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '30 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 19:36:44
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	30 Apr 2021 19:36:44
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Apr 2021 19:36:44

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '30 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '11:43'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '30 Apr 2021 11:43'	System	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '97.9' F	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered '66'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '16'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '106'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '77'	Norma Frederick (b) (4)	30 Apr 2021 19:41:16
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 19:41:16

US3792080

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 19:41:23
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 19:41:23
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:41:44

US3792080

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '30 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 19:41:44
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '12:07'	Norma Frederick (b) (4)	30 Apr 2021 19:41:44
	(b) (4)	

US3792080

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '30 Apr 2021 12:07'	System	30 Apr 2021 19:41:44

US3792080

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:41:48

US3792080

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:41:48

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:15
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
Query 'Per ETRTR: Please complete data entry within Severity Assessment page, thanks.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:49:00
User closed query 'Per ETRTR: Per CCGs Version 3.0, please consider adding new folder for NP Swab collected at 03Dec20 that resulted COVID Negative, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:29:54
Query 'Per ETRTR: Per CCGs Version 3.0, please consider adding new folder for NP Swab collected at 03Dec20 that resulted COVID Negative, thanks.' answered with 'done ' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	13 Mar 2021 20:29:58
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:04:40
User opened query 'Per ETRTR: Please complete data entry within Severity Assessment page, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 01:11:24
User opened query 'Per ETRTR: Per CCGs Version 3.0, please consider adding new folder for NP Swab collected at 03Dec20 that resulted COVID Negative, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 01:10:53
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:48:13

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:15
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:51
User entered '09:30'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:48:13

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:15
User entered '3 Dec 2020 09:30'	System	03 Dec 2020 17:48:13

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:15
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:04:50
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:48:13

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:15
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:04:53
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:48:13

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 1 (Day 1)'	Norma Frederick (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:14:43
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per CDM: Assessment Not Done is checked yet data is provided. Please review and reconcile. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:11:13
Query 'Per CDM: Assessment Not Done is checked yet data is provided. Please review and reconcile. Thankyou.' answered with 'updated' (Site from DM).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:48:55
User entered '0' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:48:45
User opened query 'Per CDM: Assessment Not Done is checked yet data is provided. Please review and reconcile. Thankyou.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:00:07
User entered '1'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Norma Frederick (b) (4)	03 Feb 2021 20:48:45
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	03 Dec 2020 17:49:25
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	03 Feb 2021 20:48:45
User entered empty.	System	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '98.2' F	(b) (4) Norma Frederick (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:07
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:12
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:10
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:16
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:19
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:17:06
User entered 'Mild (Mild)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:22
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:17:13
User entered 'Moderate (Moderate)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:25
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:27
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:30
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:32
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:35
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:37
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:39
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:18:42
User entered 'None (None)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:25

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 2 (Day 2)'	Ann Marie Milliken (b) (4)	06 Dec 2020 19:59:15
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:13
User entered '4 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:15
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:36
User entered '95'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:38
User entered '99.7' F	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:43
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:45
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:02
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:05
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:54
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:29:59
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:30:03
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:30:10
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per source, New loss of taste is mild, EDC states None. Please update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:57:29
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 20:57:26
Query 'Per source, New loss of taste is mild, EDC states None. Please update.' answered with 'updated' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:49:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:49:45
User opened query 'Per source, New loss of taste is mild, EDC states None. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 16:31:26
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:30:28
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:46
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:49
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:44
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:41
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:35
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:52
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 19:59:15

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 3 (Day 3)'	Ann Marie Milliken (b) (4)	06 Dec 2020 20:01:46
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:57
User entered '5 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:59
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:02
User entered '97'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:05
User entered '100.2' F	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:09
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:12
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:16
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:19
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:33
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:37
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:39
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:41
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:46
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:48
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:04
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:57
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:02
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:08
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:10
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:13
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:01:46

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 4 (Day 4)'	Ann Marie Milliken (b) (4)	06 Dec 2020 20:03:34
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:45
User entered '6 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:48
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:49
User entered '97'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:52
User entered '98.7' F	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:59
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:05
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:10
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:13
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:15
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:19
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:21
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:24
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:28
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:31
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:33
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:41
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:49
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:52
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:55
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:35:59
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	06 Dec 2020 20:03:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 5 (Day 5)'	Ann Marie Milliken (b) (4)	07 Dec 2020 22:34:50
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:37:06
User entered '7 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:37:08
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:13
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:15
User entered '99.2' F	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:19
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:21
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:23
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:25
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:31
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:35
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:37
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:46
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:50
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:51
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:39:58
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:40:03
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:40:08
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:40:12
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:40:14
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:40:18
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	07 Dec 2020 22:34:50

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 9 (Day 9)'	Ann Marie Milliken (b) (4)	12 Dec 2020 22:47:43
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:31
User entered '11 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:29
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:27
User entered '97'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:24
User entered '99.2' F	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:22
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:20
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:18
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:14
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:31
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:12
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:10
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:08
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:06
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:04
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:48:02
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:59
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:49
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:43
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:41
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:47:37
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:47:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 10 (Day 10)'	Ann Marie Milliken (b) (4)	12 Dec 2020 22:51:57
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:51
User entered '12 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:49
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:47
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:45
User entered '98.9' F	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:44
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:42
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:40
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:38
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:51:59
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:02
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:04
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:07
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:35
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:31
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:33
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:20
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:18
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:16
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:13
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:52:11
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	12 Dec 2020 22:51:57

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 11 (Day 11)'	Ann Marie Milliken (b) (4)	14 Dec 2020 17:02:38
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:16
User entered '13 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:18
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:21
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:24
User entered '98.7' F	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:29
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:30
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:35
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:38
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:53:04
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:40
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:42
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:44
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:48
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:50
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:52
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:03:55
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:05
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 18:04:03
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:04:01
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:07
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:09
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:53:16
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:02:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 12 (Day 12)'	(b) (4) Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:25
User entered '14 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:23
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:20
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:19
User entered '98.8' F	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:16
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:32
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:26
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:30
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:41
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:13
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:11
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:09
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:07
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:05
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:47
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:49
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:03
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:05:01
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:58
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:04:56
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	14 Dec 2020 17:31:07

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 13 (Day 13)'	Ann Marie Milliken (b) (4)	16 Dec 2020 16:45:05
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:48
User entered '15 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:44
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:42
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:40
User entered '97.6' F	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:37
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:07:00
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:58
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:56
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:24
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:54
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:52
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:27
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:50
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:47
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:42
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:45
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:40
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:37
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:35
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:06:33
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:45:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 14 (Day 14)'	Ann Marie Milliken (b) (4)	16 Dec 2020 16:57:18
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:33
User entered '16 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:31
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:30
User entered '98'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:28
User entered '98.8' F	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:24
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:22
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:19
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:17
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:49
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:14
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:12
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:10
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:08
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:06
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:03
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:01
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:59
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:57
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:55
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:54
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	16 Dec 2020 16:57:18

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 15 (Day 15)'	Ann Marie Milliken (b) (4)	17 Dec 2020 21:43:34
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:48
User entered '17 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:45
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:43
User entered '99'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:41
User entered '97.8' F	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:38
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:37
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:35
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:33
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:04
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:31
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:30
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:28
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:24
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:23
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:21
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:19
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:17
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:15
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:13
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:11
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	17 Dec 2020 21:43:34

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 16 (Day 16)'	Ann Marie Milliken	18 Dec 2020 16:32:31
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:13
User entered '18 Dec 2020'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:17
User entered '0'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:22
User entered '99'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered '%'	System	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:21
User entered '98.2' F	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:24
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:26
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:30
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:32
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:34
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:36
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:38
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:40
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:44
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:46
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:48
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:50
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:53
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:56
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:11:58
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:12:00
User entered 'None (None)'	Ann Marie Milliken (b) (4) (b) (4)	18 Dec 2020 16:32:31

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 6 (Day 6)'	Ann Marie Milliken (b) (4)	30 Dec 2020 16:07:05
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '8 Dec 2020'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'l'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered empty.	System	30 Dec 2020 16:07:05

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:05
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:05
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 7 (Day 7)'	Ann Marie Milliken (b) (4)	30 Dec 2020 16:07:33
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '9 Dec 2020'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'l'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered empty.	System	30 Dec 2020 16:07:33

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:33
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:33
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:33
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:33
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:33
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:33
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Day 8 (Day 8)'	Ann Marie Milliken (b) (4)	30 Dec 2020 16:07:54
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '10 Dec 2020'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:54
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'l'	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:54
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
User entered empty.	System	30 Dec 2020 16:07:54

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:54
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	
	Ann Marie Milliken	30 Dec 2020 16:07:54
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:49:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:21
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:41:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4)	30 Dec 2020 16:07:54
	Ann Marie Milliken	
	(b) (4)	
	(b) (4)	

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
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)	24 Dec 2020 06:22:50
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 'updated AE form ' (Site from System).	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 22:28:28
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 22:28:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 22:28:14
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 22:28:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 22:28:14
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:49:47
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User closed query 'Per ETRTR: Please consider adding date of Test when COVID was positive, i.e. 05Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:12:46
Query 'Per ETRTR: Please consider adding date of Test when COVID was positive, i.e. 05Dec20, thanks.' answered with 'updated to correct date' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:22:50
User entered '5 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:22:42
User opened query 'Per ETRTR: Please consider adding date of Test when COVID was positive, i.e. 05Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 01:08:25
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User closed query 'Per ETRTR: Saliva sample was the Type of test that resulted COVID + according to Preclarus Lab Portal. Consider updating answer as applcaible.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:13:01
Query 'Per ETRTR: Saliva sample was the Type of test that resulted COVID + according to Preclarus Lab Portal. Consider updating answer as applcaible.' answered with 'corrected type of test to saliva ' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:23:01
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:22:42
User opened query 'Per ETRTR: Saliva sample was the Type of test that resulted COVID + according to Preclarus Lab Portal. Consider updating answer as applcaible.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 01:09:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[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)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:22:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:49:47

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:26
User entered 'I'	System	14 Dec 2020 22:28:14

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Start Date](#)

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US3792080

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[End Date](#)

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US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
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US3792080

Folder: Covid-19 Assessment 03 Dec 2020

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Generated On: 10 Jun 2021 09:49:54

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
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US3792080

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US3792080

Folder: Covid-19 Assessment 03 Dec 2020

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[Heart Rate](#)

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US3792080

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
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US3792080

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US3792080

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[Oxygen Saturation](#)

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US3792080

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
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US3792080

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[PaO2](#)

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US3792080

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[Did the subject have Respiratory failure?](#)

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US3792080

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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US3792080

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US3792080

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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US3792080

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[ECMO?](#)

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US3792080

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
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US3792080

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[Evidence of Shock Requires
Vasopressors](#)

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US3792080

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[Acute Renal Dysfunction?](#)

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US3792080

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[Hepatic Dysfunction?](#)

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US3792080

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[Neurologic Dysfunction?](#)

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US3792080

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Generated On: 10 Jun 2021 09:49:54

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:49:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:30
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:27:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Jan 2021 22:42:38

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:49:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:24
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	20 Feb 2021 02:19:57
Signature has been broken.	(b) (4) Norma Frederick (b) (4)	20 Feb 2021 01:53:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Norma Frederick (b) (4)	20 Feb 2021 01:53:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 20:30:21

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:41
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:38
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:22:23

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:41
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:38
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:22:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:22:51
User entered '09:30' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:22:51
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:22:23
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:22:23

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:41
User entered '3 Dec 2020 09:30'	System	20 Feb 2021 02:22:51
User entered empty.	System	20 Feb 2021 02:22:23

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:41
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:38
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:22:23

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:41
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:38
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:22:23

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:27:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:27:09
User entered '3 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:27:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:23:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:27:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:27:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:27:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:23:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:27:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:27:09
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:27:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:23:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:27:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:27:09
User entered '3 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:27:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:23:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:27:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 02:27:09
User entered 'Nasal Swab (Nasal Swab)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:27:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 02:23:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[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)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:43:16
User entered empty.	Norma Frederick (b) (4) (b) (4)	20 Feb 2021 02:23:43

US3792080

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:49:54

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:34:46
User entered '0'	System	20 Feb 2021 02:27:09

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 3 (Day 3)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:47:31
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:47:34
User entered '5 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 5 (Day 5)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:43
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:45
User entered '7 Dec 2020'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 7 (Day 7)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:25
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	14 Dec 2020 22:31:46
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	Norma Frederick (b) (4)	09 Dec 2020 19:07:31
	(b) (4)	

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:25
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 9 (Day 9)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 22:31:46
User entered 'NA (COVID-19 Negative) (NA)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:22
User entered '11 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Dec 2020 22:31:46
User entered empty.	(b) (4) Norma Frederick (b) (4)	09 Dec 2020 19:07:31
	(b) (4)	

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 14 (Day 14)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:47:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	03 Feb 2021 20:43:53
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Norma Frederick (b) (4)	09 Dec 2020 19:07:31
	(b) (4)	

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:01
User entered '16 Dec 2020' reason for change: New Information	Norma Frederick (b) (4)	03 Feb 2021 20:43:53
User entered empty.	(b) (4) Norma Frederick (b) (4)	09 Dec 2020 19:07:31
	(b) (4)	

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 21 (Day 21)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	03 Feb 2021 20:42:37
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Norma Frederick (b) (4)	29 Jan 2021 20:13:47
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 21:39:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:39:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	15 Jan 2021 21:39:21
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 22:31:46
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	14 Dec 2020 22:31:46
User entered 'NA (COVID-19 Negative) (NA)'	Norma Frederick (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:33
User entered '23 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	03 Feb 2021 20:42:37
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	29 Jan 2021 20:13:47
User entered '23 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	15 Jan 2021 21:39:21
User entered empty.	Norma Frederick (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:49:54

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
User accepted default value 'Day 28 (Day 28)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:49:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
Signature has been broken.	(b) (4) Norma Frederick (b) (4)	13 Mar 2021 20:12:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Norma Frederick (b) (4)	13 Mar 2021 20:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4) Norma Frederick (b) (4)	29 Jan 2021 20:11:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 21:39:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:39:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:39:21
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 22:31:46
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 22:31:46
User entered 'NA (COVID-19 Negative) (NA)'	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Convalescence visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 06:01:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Convalescence visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'edc updated ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	13 Mar 2021 20:13:04
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	13 Mar 2021 20:12:46
User entered '30 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	13 Mar 2021 20:12:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Convalescence visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:36:42
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 30DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:48:28

US3792080

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: Saliva: Samples dated 30DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled in PPD central lab. Please confirm the correct visit, Thank you.' answered with 'no saliva collected ; only blood draw. Site used Unscheduled Kit for Convalescent Day 28' (Site from DM). User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	29 Jan 2021 20:12:28
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 30DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM). User entered '30 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4), (b) (6)	29 Jan 2021 20:11:57 27 Jan 2021 07:49:21
User entered empty.	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:39:21
	Norma Frederick (b) (4) (b) (4)	09 Dec 2020 19:07:31

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:45
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Unscheduled visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 05:56:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Unscheduled visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with '30Dec2020 Saliva sample is listed under saliva collection log - Day 28.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 20:51:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:30:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Unscheduled visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 07:37:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:45
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 05:56:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with '16Dec2020 Saliva sample is listed under saliva collection log - Day 14.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 20:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:30:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:42:09
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:45
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:30:20
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:45
User entered 'SICKD1'	System	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:08:44
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:31:06
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' answered with 'updated edc' (Site from DM).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:45:51
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:49:50
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '09:44'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User entered '3 Dec 2020 09:44'	System	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '70.75' in	Norma Frederick (b) (4)	03 Dec 2020 17:51:38
DataPoint set to visible.	(b) (4) System	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '172.0' lb	Norma Frederick (b) (4)	03 Dec 2020 17:51:38
DataPoint set to visible.	(b) (4) System	03 Dec 2020 17:50:30

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '98.2' F	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '70'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User entered 'bpm'	System	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '16'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User entered 'breaths/min'	System	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '112'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User entered 'mmHg'	System	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:06
User entered '79'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56
User entered 'mmHg'	System	03 Dec 2020 17:51:38

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:01:56

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:01
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:45

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:01
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:52
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	03 Dec 2020 17:51:59
User entered '3 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:59
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	03 Dec 2020 17:51:45
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:51:45

US3792080

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:05
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:36:11
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:52:11

US3792080

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:05
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 06:42:25
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:36:11
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated edc' (Site from DM).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:44:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:37:17
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:52:11

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:35:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:35:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	02 Apr 2021 22:35:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	02 Apr 2021 22:35:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '11:40'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '2 Apr 2021 11:40'	System	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	
DataPoint set to visible.	System	02 Apr 2021 22:35:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	
DataPoint set to visible.	System	02 Apr 2021 22:35:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '98.0' F	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:50:53
User entered empty.	Norma Frederick (b) (4) (b) (4)	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '60'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '16'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '118'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '77'	Norma Frederick (b) (4)	02 Apr 2021 22:36:40
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 22:36:40

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:36:46
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:36:46
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:36:56
	(b) (4)	

US3792080

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:36:56
	(b) (4)	

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:12
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:38:07
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:12
User closed query 'Per CDM: Please clarify entry, as visit Safety Call Day 85 shares same date with Convalescence visit day 28 and should contain the same data' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 20:27:37
Query 'Per CDM: Please clarify entry, as visit Safety Call Day 85 shares same date with Convalescence visit day 28 and should contain the same data' answered with 'Safety call day 85 completed in conjunction with D 28 convalescence visit in clinic.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:31:06
User opened query 'Per CDM: Please clarify entry, as visit Safety Call Day 85 shares same date with Convalescence visit day 28 and should contain the same data' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:48:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:38:07
User entered '30 Dec 2020'	Norma Frederick (b) (4)	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:12
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:38:07
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:12
User entered 'SICKD28'	System	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '30 Dec 2020'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '09:15'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User entered '30 Dec 2020 09:15'	System	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	15 Jan 2021 21:37:00
DataPoint set to visible.	(b) (4) System	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	15 Jan 2021 21:37:00
DataPoint set to visible.	(b) (4) System	15 Jan 2021 21:27:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '97.5' F	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered empty.	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '52'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User entered 'bpm'	System	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '14'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User entered 'breaths/min'	System	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '124'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User entered 'mmHg'	System	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:39:43
User entered '84'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17
User entered 'mmHg'	System	15 Jan 2021 21:37:00

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:17

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:22
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:42:40
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:30

US3792080

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:22
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:42:40
User entered '30 Dec 2020'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:37:30

US3792080

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:43:15
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:38:33

US3792080

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:49:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:02:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:43:15
User closed query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4), (b) (6)	01 Feb 2021 17:26:49
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	Norma Frederick (b) (4) (b) (4)	29 Jan 2021 20:14:28
' answered with 'site used unscheduled lab kit for this visit ' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4), (b) (6)	27 Jan 2021 16:02:16
' (Site from DM).		
User entered '30 Dec 2020'	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:38:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

2294 of 3053

US3792080

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:14:46

US3792080

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:14:46

US3792080

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	29 Jan 2021 20:14:46

US3792080

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 20:14:46

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:20:23

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:20:23

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '1'	System	29 Jan 2021 20:15:08

US3792080

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'I'	System	29 Jan 2021 20:15:08

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	29 Jan 2021 20:27:23
DataPoint set to visible.	System	29 Jan 2021 20:15:08

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	29 Jan 2021 20:27:23
DataPoint set to visible.	System	29 Jan 2021 20:15:08

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '10:21'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '29 Jan 2021 10:21'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '97.6' F	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '47'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'bpm'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '16'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'breaths/min'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '131'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '85'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	29 Jan 2021 20:27:23
DataPoint set to visible.	System	29 Jan 2021 20:15:08

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '11:59'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '29 Jan 2021 11:59'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '98.0' F	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '50'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'bpm'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '16'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'breaths/min'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '134'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '91'	Norma Frederick (b) (4)	29 Jan 2021 20:27:23

US3792080

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mmHg'	System	29 Jan 2021 20:27:23

US3792080

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:15

US3792080

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:15:15

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Urine (URINE)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Negative (NEGATIVE)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:15:30

US3792080

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered empty.	System	29 Jan 2021 20:15:30

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'mRNA-1273'	System	29 Jan 2021 20:16:14
DataPoint set to visible.	System	29 Jan 2021 20:15:08

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '11:28'	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '29 Jan 2021 11:28'	System	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'ONCE'	System	29 Jan 2021 20:16:14

US3792080

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

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 20:16:14

US3792080

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:16:38

US3792080

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:16:38

US3792080

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '10:30'	Norma Frederick (b) (4)	29 Jan 2021 20:16:38

US3792080

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '29 Jan 2021 10:30'	System	29 Jan 2021 20:16:38

US3792080

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:16:53

US3792080

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Jan 2021'	Norma Frederick (b) (4)	29 Jan 2021 20:16:53

US3792080

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '10:35'	Norma Frederick (b) (4)	29 Jan 2021 20:16:53

US3792080

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered '29 Jan 2021 10:35'	System	29 Jan 2021 20:16:53

US3792080

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

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	29 Jan 2021 20:17:00

US3792080

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

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:19
User entered 'I'	System	29 Jan 2021 20:17:00

US3792080

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
	(b) (4)	
User entered 'Yes (Y)'	Ann Marie Milliken	05 Feb 2021 21:46:26
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
	(b) (4)	
User entered '5 Feb 2021'	Ann Marie Milliken	05 Feb 2021 21:46:26
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken	05 Feb 2021 21:46:26
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
	(b) (4)	
User entered empty.	Ann Marie Milliken	05 Feb 2021 21:46:26
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:14
	(b) (4)	
User entered 'Yes (Y)'	Ann Marie Milliken	05 Feb 2021 21:46:32
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User entered 'I'	System	05 Feb 2021 21:46:32

US3792080

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:21
User entered 'I'	System	05 Feb 2021 21:46:32
DataPoint set to visible.	System	05 Feb 2021 21:46:32

US3792080

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:26:34

US3792080

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '26 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:26:34

US3792080

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	26 Feb 2021 18:26:34

US3792080

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'OLD29'	System	26 Feb 2021 18:26:34

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:13
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '26 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '09:30'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:13
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered '26 Feb 2021 09:30'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '97.8' F	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Oral (Oral)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:13
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '53'	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'bpm'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '16'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'breaths/min'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '117'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'mmHg'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '75'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'mmHg'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '26 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '10:47'	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered '26 Feb 2021 10:47'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '97.7' F	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Oral (Oral)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:13
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:13
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '57'	Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'bpm'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '16'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'breaths/min'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '113'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'mmHg'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '75'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'mmHg'	System	26 Feb 2021 18:28:13

US3792080

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'No (N)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:17
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:17
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered 'Yes (Y)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:28
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered '26 Feb 2021'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:28
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered 'Urine (URINE)'	Norma Frederick (b) (4)	26 Feb 2021 18:28:28

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered 'Negative (NEGATIVE)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:28

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User closed query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4)	
Query 'per CDM: please input yes or no for this field' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:52:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 05:48:14
User opened query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:47:46
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 20:48:59
	Norma Frederick (b) (4)	26 Feb 2021 18:28:28
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:28
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:28
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered empty.	System	26 Feb 2021 18:28:28

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:28:59
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'mRNA-1273'	System	26 Feb 2021 18:28:59
DataPoint set to visible.	System	05 Feb 2021 21:46:32

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '26 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '10:15'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered '26 Feb 2021 10:15'	System	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'ONCE'	System	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 18:28:59

US3792080

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 18:29:05
	(b) (4)	

US3792080

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:36
User entered 'I'	System	26 Feb 2021 18:29:05

US3792080

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 18:48:12
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered '5 Mar 2021'	Ann Marie Milliken	05 Mar 2021 18:48:12
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Ann Marie Milliken	05 Mar 2021 18:48:12
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered empty.	Ann Marie Milliken	05 Mar 2021 18:48:12
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:54:30
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 18:48:18
	(b) (4)	
	(b) (4)	

US3792080

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:51
User entered 'I'	System	05 Mar 2021 18:48:18

US3792080

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:31:38
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:31:38
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	02 Apr 2021 22:31:38
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	02 Apr 2021 22:31:38

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:50:53
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '11:40'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '2 Apr 2021 11:40'	System	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '98.0' F	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '60'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '16'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '118'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '77'	Norma Frederick (b) (4)	02 Apr 2021 22:32:15
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 22:32:15

US3792080

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:32:33
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:32:33
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Apr 2021 22:32:43
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2 Apr 2021'	Norma Frederick (b) (4)	02 Apr 2021 22:32:43
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '12:15'	Norma Frederick (b) (4)	02 Apr 2021 22:32:43
	(b) (4)	

US3792080

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '2 Apr 2021 12:15'	System	02 Apr 2021 22:32:43

US3792080

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:49:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:13:17
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Apr 2021 01:43:11
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'per sub I note on day 8 subject states these aches are just from sitting too long at work' (Site from DM).	Norma Frederick (b) (4) (b) (4)	17 Apr 2021 00:33:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:57:57
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 09:56:21
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:05:26

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Nasopharyngitis, LLT: Common cold - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:28:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:28:25
Data point term sent to Coder	System	04 Nov 2020 17:11:51
User entered 'COMMON COLD'	Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '29 Oct 2020'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
User entered empty.	System	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '30 Oct 2020'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
User entered empty.	System	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'None (NONE)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'l'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'HAD COVID 19 TEST DONE AND IT WAS NEGATIVE'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
User entered '0'	System	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12
User entered '0'	System	04 Nov 2020 17:11:05

US3792080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:12

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:14:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered	(b) (4)	15 Dec 2020 15:01:29
'USA-US057-2020-mRNA-1273-P301000003'	System	15 Dec 2020 15:01:29
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 15:01:29

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
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)	14 Dec 2020 21:58:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 21:58:51
Data point term sent to Coder	System	14 Dec 2020 21:57:59
User entered 'COVID-19'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 23:17:36
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 03 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 18:31:28
Query 'PV Query: COVID-19 symptoms have been reported starting on 03 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:46:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:46:09
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:46:09
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 15:46:09
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 03 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:03:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 22:10:21
Signature has been broken.	Norma Frederick (b) (4)	16 Apr 2021 22:06:41
	(b) (4)	
User entered '5 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	16 Apr 2021 22:06:41
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User closed query 'PV Query: Please consider updating event start date to onset date of symptoms (03 Dec 2020).' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 16:01:35
Query 'PV Query: Please consider updating event start date to onset date of symptoms (03 Dec 2020).' answered with 'updated' (Site from Safety).	Bettie Corcoran (b) (4)	23 Dec 2020 22:24:55
	(b) (4)	
User entered '3 Dec 2020' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	23 Dec 2020 22:24:48
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

2519 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating event start date to onset date of symptoms (03 Dec 2020).' ' (Site from Safety).<br/ User entered '5 Dec 2020'	(b) (4), (b) (6) (b) (6)	21 Dec 2020 19:42:40
	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per MM, please provide the end date.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:07:31
Query 'Per MM, please provide the end date.	Norma Frederick (b) (4)	03 Feb 2021 20:34:45
' answered with 'end date entered ' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	03 Feb 2021 20:34:23
User opened query 'Per MM, please provide the end date.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:25:39
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: End date is reported as 31 Dec 2020. Subject was asymptomatic starting on 18 Dec 2020. Per protocol, event end date is the day of subject becoming asymptomatic. Please reassess event end date.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	03 May 2021 16:21:15
DataPoint Verified.	Abram Burgher (b) (4) (b) (4), (b) (6)	29 Apr 2021 15:12:13
DataPoint Un-verified.	(b) (4)	26 Apr 2021 23:17:36
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:00:41
User entered '31 Dec 2020' reason for change: Data Entry Error DataPoint Verified.	Norma Frederick (b) (4) (b) (4), (b) (6)	26 Apr 2021 23:00:41
User signature succeeded.	(b) (4)	16 Apr 2021 22:10:21
User entered '21 Dec 2020' reason for change: Data Entry Error 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). 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 'subject reports symptoms were ongoing at last visit (day 28 convalescent)' (Site from Safety).	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:34:23
	(b) (4), (b) (6)	19 Jan 2021 15:27:37
	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:20:01
	(b) (4), (b) (6)	21 Dec 2020 19:42:24
	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query '. PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:46:53
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)	25 Jan 2021 21:19:01
User entered empty.	System	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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	23 Apr 2021 19:25:07
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	23 Apr 2021 19:23:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:10:21
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	16 Apr 2021 22:07:53
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	16 Apr 2021 22:07:26
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 22:07:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 22:07:26
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	26 Jan 2021 21:23:46
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 23:17:36
User closed query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly. ' (Site from Safety). Query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly. ' answered with 'covid 19 is an SAE per protocol. Please clarify if this SAE should not be reported. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 18:31:49
User entered '1' reason for change: Data Entry Error	Norma Frederick (b) (4)	23 Apr 2021 19:25:44
	(b) (4)	
DataPoint Un-verified.	Norma Frederick (b) (4)	23 Apr 2021 19:25:07
	(b) (4)	
Signature has been broken.	Norma Frederick (b) (4)	23 Apr 2021 19:23:26
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Norma Frederick (b) (4)	23 Apr 2021 19:23:26
	(b) (4)	
User opened query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:04:09
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
Signature has been broken.	Norma Frederick (b) (4)	16 Apr 2021 22:07:53
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Norma Frederick (b) (4)	16 Apr 2021 22:07:53
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

2538 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Jan 2021 21:23:46
	(b) (4)	
User entered '1'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Dec 2020 22:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 22:02:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Dec 2020 22:02:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Dec 2020 21:57:21
User entered empty.	System	14 Dec 2020 21:57:21
	Norma Frederick (b) (4)	14 Dec 2020 21:57:21
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Dec 2020 22:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 22:02:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Dec 2020 22:02:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Dec 2020 21:57:21
User entered empty.	System	14 Dec 2020 21:57:21
	Norma Frederick (b) (4)	14 Dec 2020 21:57:21
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:34:23
User entered '1'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	03 Feb 2021 20:34:23
User entered '0'	(b) (4)	
	Norma Frederick (b) (4)	14 Dec 2020 21:57:21
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '0'	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:23:46
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).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:34:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:34:23
Data Entry Error		
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)	25 Jan 2021 21:18:40
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:27:43
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 'subject's symptoms were ongoing at day 28 convalescent visit ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:20:30
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)	21 Dec 2020 19:42:58
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 21:57:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 21:57:57

PRODUCTION RELEASE (v12.003
EAB) (1725)

2546 of 3053

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Dec 2020 21:57:57
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 21:57:21
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:10:21
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'PV Query: Thank you for confirming positive swab on day 3. Please consider updating COVID Diagnostic Test form.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:37
Query 'PV Query: Thank you for confirming positive swab on day 3. Please consider updating COVID Diagnostic Test form.' answered with 'form updated ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	26 Jan 2021 21:24:40
User opened query 'PV Query: Thank you for confirming positive swab on day 3. Please consider updating COVID Diagnostic Test form.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 19:30:03
User closed query 'PV Query: Please confirm the positive nasopharyngeal swab on 03 Dec 2020, as the narrative indicated the subject had a negative PCR swab but a positive Day 3 saliva test. Please update the diagnostic testing or narrative as applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 16:01:55
Query 'PV Query: Please confirm the positive nasopharyngeal swab on 03 Dec 2020, as the narrative indicated the subject had a negative PCR swab but a positive Day 3 saliva test. Please update the diagnostic testing or narrative as applicable.' answered with 'confirmed, day 1 swab negative, day 3 saliva positive.' (Site from Safety).	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 22:30:54
User opened query 'PV Query: Please confirm the positive nasopharyngeal swab on 03 Dec 2020, as the narrative indicated the subject had a negative PCR swab but a positive Day 3 saliva test. Please update the diagnostic testing or narrative as applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:43:25
User entered 'SUBJECT HAD A NEGATIVE PCR SWAB BUT DAY 3 SALIVA WAS POSITIVE.' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 21:57:57
User entered 'SUBJECT HAD A NEGATIVE PCR SWAB BUT DAY 3 SALIVA WAS POSTIVE.'	Norma Frederick (b) (4) (b) (4)	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 22:07:26
User entered '0'	System	26 Jan 2021 21:23:46
User entered '1'	System	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 21:57:21

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Aphthous ulcer, LLT: Canker sores oral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 23:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 23:10:49
Data point term sent to Coder	System	26 Apr 2021 23:05:06
User entered 'minor canker sore, left lateral tongue'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '28 Dec 2020'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User entered empty.	System	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '31 Dec 2020'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User entered empty.	System	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Related (RELATED)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Related (RELATED)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Not Applicable (NOT APPLICABLE)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'l'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User entered '0'	System	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21
User entered '0'	System	26 Apr 2021 23:04:41

US3792080

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:21

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
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) (b) (4)	26 Apr 2021 23:08:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 23:08:45
Data point term sent to Coder	System	26 Apr 2021 23:08:07
User entered 'arthralgia'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '07 Oct 2020'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User entered empty.	System	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '10 Oct 2020'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User entered empty.	System	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Apr 2021 22:31:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 22:31:03
DataPoint Un-verified.	Norma Frederick (b) (4)	28 Apr 2021 22:31:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 22:31:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 23:17:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 23:07:40
User entered empty.	Norma Frederick (b) (4)	26 Apr 2021 23:07:40
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Apr 2021 22:31:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 22:31:03
DataPoint Un-verified.	Norma Frederick (b) (4)	28 Apr 2021 22:31:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 22:31:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 23:17:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 23:07:40
User entered empty.	Norma Frederick (b) (4)	26 Apr 2021 23:07:40
	(b) (4)	

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Not Applicable (NOT APPLICABLE)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'l'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered '0'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered empty.	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 23:17:36
User entered 'AE reported per EDC query as subject reported this in her diary and not to the site at a clinic visit'	Norma Frederick (b) (4) (b) (4)	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User entered '0'	System	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26
User entered '0'	System	26 Apr 2021 23:07:40

US3792080

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:17:26

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 19:45:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 19:45:13
Data point term sent to Coder	System	30 Apr 2021 19:44:20
User entered 'worsened seasonal allergies'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User entered '31 Mar 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	30 Apr 2021 19:46:53
User entered '02 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Apr 2021 19:44:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Apr 2021 19:44:41
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	30 Apr 2021 19:44:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Apr 2021 19:44:02
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Apr 2021 19:44:02
User entered 'un:un' (non-conformant).	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:44:41
User entered '02 Apr 2021 UN:UN' (non-conformant).	System	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[None](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Norma Frederick (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 19:44:02

US3792080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:49:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 19:44:02

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:49:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:13:17
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:48:58

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 19:51:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:51:38
Data point term sent to Coder	System	30 Sep 2020 19:50:45
User entered 'sertraline'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'depression'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '100'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'un Mar 2020'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:50:11
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 19:50:11

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 19:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 19:52:38
Data point term sent to Coder	System	30 Sep 2020 19:51:47
User entered 'Allegra'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'seasonal allergies'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '10'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:51:19

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'un UNK 2019'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:51:19
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:51:19

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:51:19

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:51:19

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 14:29:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:29:41
Data point term sent to Coder	System	30 Sep 2020 19:52:48
User entered 'Musinex ER'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'seasonal allergies'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '750'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'un UNK 2019'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:52:04
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:52:04

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
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.	(b) (4) Coder Import (b) (4)	01 Oct 2020 04:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:15:42
Data point term sent to Coder	System	30 Sep 2020 19:53:49
User entered 'albuterol inhaler'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'seasonal asthma'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 10:46:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated per subject report' (Site from DM).	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 20:35:42
User entered '90' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 20:35:20
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:58:51
User entered '2'	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	03 Dec 2020 20:35:20
User entered 'puff (PUFF)'	(b) (4)	
	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Feb 2021 21:59:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'un UNK 2010'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Sep 2020 19:53:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:53:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 17:15:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 17:15:26
Data point term sent to Coder	System	04 Nov 2020 17:15:00
User entered 'FLU VACCINE'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '1'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Other (OTHER)'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'INJECTION'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'once (ONCE)'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Norma Frederick (b) (4)	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '15 Oct 2020'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '15 Oct 2020'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 17:14:50
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:14:50

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL COLD + COUGH + SORE THROAT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 11:35:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:35:36
Data point term sent to Coder	System	04 Nov 2020 17:24:12
User entered 'TYLENOLD COLD ACETAMINOPHEN/DEXTROMETHORPHAN'	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 17:24:00

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'COMMON COLD'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '325/10'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '29 Oct 2020'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '30 Oct 2020'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 17:24:00
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:24:00

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:24:00

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:24:00

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Jan 2021 21:43:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Jan 2021 21:43:53
Data point term sent to Coder	System	15 Jan 2021 21:46:07
Coding entries removed.	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:45:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL COLD + COUGH + SORE THROAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:42:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:42:58
Data point term sent to Coder	System	03 Dec 2020 17:54:44
User entered 'Tylenol Cold and Flu Acetaminophen/dextromethorphan'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:54:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:12:04
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated AE lpg ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:33:10
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:24:28
User entered 'COVID 19' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	15 Jan 2021 21:45:42
User entered 'Covid 19 symptoms'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 17:54:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug with four components; however, only two components has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 325/10/5/100).' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:24:17
Query 'Per DM CLR: Please note, this is a combination drug with four components; however, only two components has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 325/10/5/100).'	Norma Frederick (b) (4)	02 Apr 2021 22:33:46
answered with 'THIS DRUG HAS TWO INGREDIENTS AND BOTH ARE LISTED' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug with four components; however, only two components has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 325/10/5/100).' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:12:22
Un-reviewed for Data Management.	(b) (4), (b) (6)	04 Mar 2021 15:12:17
Reviewed for Data Management.	(b) (4), (b) (6)	04 Mar 2021 15:12:07
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '325/10'	(b) (4)	
	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '3 Dec 2020'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Norma Frederick (b) (4)	29 Jan 2021 20:28:22
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '04 Dec 2020' reason for change: New Information	Norma Frederick (b) (4)	29 Jan 2021 20:28:22
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	03 Dec 2020 17:54:14
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Dec 2020 17:54:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Dec 2020 17:54:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Dec 2020 17:54:14

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 20:30:22
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 Jan 2021 20:30:22
Data point term sent to Coder	System	29 Jan 2021 20:29:32
User entered 'ibuprofen'	Norma Frederick (b) (4) (b) (4)	29 Jan 2021 20:29:17

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Covid-19'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '400'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '05 Dec 2020'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '21 Dec 2020'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	29 Jan 2021 20:29:17
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:29:17

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:29:17

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:29:17

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Feb 2021 17:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:04:27
Data point term sent to Coder	System	26 Feb 2021 18:54:08
User entered 'Vitamin D'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 18:53:39

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered 'vitamin D deficiency prophylaxis'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:53:39

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '2000'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'IU (IU)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'un UNK 2017'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 18:53:39
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 18:53:39

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 18:53:39

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 18:53:39

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Feb 2021 17:09:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:09:27
Data point term sent to Coder	System	26 Feb 2021 18:55:09
User entered 'Vitamin B12'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 18:54:26

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
User entered 'vitamin B deficiency prophylaxis'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 18:54:26

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '1000'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'ug (ug)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'un UNK 2017'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:50:53
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 18:54:26
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 18:54:26

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 18:54:26

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 18:54:26

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 May 2021 15:43:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:43:59
Data point term sent to Coder	System	30 Apr 2021 19:53:25
User entered 'ibuprofen'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User entered 'worsened seasonal allergies'	(b) (4) Norma Frederick (b) (4)	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '400'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '31 Mar 2021'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 19:52:28
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 19:52:28

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: DEXTROMETHORPHAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 12:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 12:56:39
Data point term sent to Coder	System	30 Apr 2021 20:02:34
User entered 'dextromethorphan'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User entered 'worsened seasonal allergies'	(b) (4) Norma Frederick (b) (4)	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '15'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '09 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 20:02:23
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:02:23

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA D - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 12:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 12:12:38
Data point term sent to Coder	System	30 Apr 2021 20:04:35
User entered 'Allegra -D fexofenadine hcl/pseudophenedrine hcl'	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
User entered 'worsened seasonal allergies'	(b) (4) Norma Frederick (b) (4)	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '180/240'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	03 May 2021 17:06:49
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '09 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered '09 Apr 2021'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	03 May 2021 17:06:49
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	30 Apr 2021 20:03:53
	(b) (4)	

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 20:03:53

US3792080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:49:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	03 Feb 2021 20:30:35
	(b) (4)	

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '15/Dec/2020 10:01'	(b) (4) System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:49:54

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)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:55
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '28/Dec/2020 11:02'	(b) (4) System	28 Dec 2020 16:02:24

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:49:54

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)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 16:02:24

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '19/Jan/2021 10:28'	(b) (4) System	19 Jan 2021 15:28:46

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:49:54

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)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 15:28:46

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '01/Feb/2021 10:10'	(b) (4) System	01 Feb 2021 15:10:53

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:49:54

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)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:25:58
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 15:10:53

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
User entered '04/Feb/2021 09:24'	(b) (4) System	04 Feb 2021 14:24:31

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:49:54

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)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:25:58
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 14:24:31

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
User entered '19/Apr/2021 15:35'	(b) (4) System	19 Apr 2021 19:35:56

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 19:35:56

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
User entered '26/Apr/2021 14:34'	(b) (4) System	26 Apr 2021 18:34:03

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:34:03

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'USA-US057-2020-MRNA-1273-P301000003'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:49:54
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'No (N)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:49
User entered 'Yes (Y)'	System	23 Apr 2021 19:25:07
Un-reviewed for Safety.	System	23 Apr 2021 19:23:26
DataPoint Un-verified.	System	23 Apr 2021 19:23:26
Signature has been broken.	System	23 Apr 2021 19:23:26
User entered 'No (N)'	System	23 Apr 2021 19:23:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:35:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:08:31
Un-reviewed for Safety.	System	16 Apr 2021 22:07:53
Signature has been broken.	System	16 Apr 2021 22:07:53
User entered 'Yes (Y)'	System	16 Apr 2021 22:07:53
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:10:46
Un-reviewed for Safety.	System	26 Jan 2021 21:23:46
User entered 'No (N)'	System	26 Jan 2021 21:23:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Yes (Y)'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Abram'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Burgher'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '3900 East Camelback Road'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered 'Phoenix'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:28:51
User entered empty.	System	19 Jan 2021 15:28:46
User entered 'Arizona'	Norma Frederick (b) (4) (b) (4)	05 Jan 2021 23:14:52

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:44
User entered '85018'	System	15 Dec 2020 15:01:29

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:08:31
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 16:02:12
User entered 'US'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 14:16:28
User entered '7'	System	26 Apr 2021 18:34:03
User entered '6'	System	19 Apr 2021 19:35:56
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:10
	(b) (4)	
User entered '5'	System	04 Feb 2021 14:24:31
User entered '4'	System	01 Feb 2021 15:10:53
User entered '3'	System	19 Jan 2021 15:28:46
User entered '2'	System	28 Dec 2020 16:02:24
User entered '1'	System	15 Dec 2020 15:01:50

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:49:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
User entered '27/Apr/2021 10:16'	(b) (4) System	27 Apr 2021 14:16:28

US3792080

Folder: SAE USA-US057-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:49:54

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)	28 Apr 2021 22:05:13
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:43:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:16:28