

US3792090 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

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US3792090

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

Participant ID

US3792090

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

US3792090

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3792090

Folder: Screening

Form: Demographics

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female <input type="radio"/> Male <input checked="" 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

US3792090

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 01 Apr 2021 21:02:07

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Date of Informed Consent (*dd MMM yyyy*) 7 OCT 2020

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3792090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Condition	RIGHT KNEE JOINT PAIN
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3792090

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Condition	RIGHT ANKLE JOINT PAIN
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3792090

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:37 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:37
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	286.8 lb
BMI (<i>xxx.x</i>)	35.92250 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

7 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Apr 2021 21:02:07

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes No

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes No

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes No

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes No

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes No

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes No

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes No

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes No

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes No

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes No

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes No

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Apr 2021 21:02:07

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 7 OCT 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

What was the date of randomization? (dd MMM yyyy) 07 OCT 2020

What was the participant's randomization number? 116372

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Height	ND - Not Done
Weight	ND - Not Done

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:37 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:37
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:29 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:29
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	61 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>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 12:52 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 12:52

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

US3792090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	7 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:31 (24 HR)
Collection date and time (derived)	7 OCT 2020 12:31

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Collection date (<i>dd MMM yyyy</i>)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	7 OCT 2020 12:35
Nasopharyngeal Swab 2	No		

US3792090

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 07 OCT 2020 13:30
PC Open Date & Time 07 OCT 2020 13:12
PC Close Date & Time 07 OCT 2020 15:42

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 98.5 °F

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

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

PC Time Stamp 07 OCT 2020 19:14
PC Open Date & Time 07 OCT 2020 16:37
PC Close Date & Time 08 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 OCT 2020 19:44
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 20:43
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 21:21
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 OCT 2020 21:09
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 OCT 2020 21:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 OCT 2020 23:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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	07 OCT 2020 13:31
PC Open Date & Time	07 OCT 2020 13:12
PC Close Date & Time	07 OCT 2020 15:42

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

07 OCT 2020 19:15

PC Open Date & Time

07 OCT 2020 16:37

PC Close Date & Time

08 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	08 OCT 2020 19:42
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 OCT 2020 20:43

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

10 OCT 2020 21:19

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 OCT 2020 21:08
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 OCT 2020 21:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 OCT 2020 23:06

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

No

Yes

PC Time stamp	07 OCT 2020 13:31
PC Open Date & Time	07 OCT 2020 13:12
PC Close Date & Time	07 OCT 2020 15:42

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

No

Yes

PC Time stamp	07 OCT 2020 19:16
PC Open Date & Time	07 OCT 2020 16:37
PC Close Date & Time	08 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 19:42
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 20:43
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 21:19
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 21:07
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 21:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	13 OCT 2020 23:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3792090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 5 NOV 2020

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

Folder OID VISIT2

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	5 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 09:18
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	5 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:26 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 10:26
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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) 5 NOV 2020

What was the treatment time? (00:00-23:59) 09:43 (24 HR)

Treatment Date and Time (derived) 5 NOV 2020 09:43

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

What was the frequency of the study treatment dosing? ONCE

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

US3792090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 5 NOV 2020

Collection time (*00:00-23:59*) 09:26 (24 HR)

Collection date and time (derived) 5 NOV 2020 09:26

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Collection date (<i>dd MMM yyyy</i>)			5 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	5 NOV 2020 09:30
Nasopharyngeal Swab 2	No		

US3792090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 98.1 °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 05 NOV 2020 10:26

PC Open Date & Time 05 NOV 2020 10:03

PC Close Date & Time 05 NOV 2020 12:33

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	05 NOV 2020 22:51
PC Open Date & Time	05 NOV 2020 13:28
PC Close Date & Time	06 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 NOV 2020 15:36
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 NOV 2020 17:30
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 NOV 2020 21:38
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 NOV 2020 20:09
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 NOV 2020 05:07
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 NOV 2020 17:42
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

05 NOV 2020 10:26

PC Open Date & Time

05 NOV 2020 10:03

PC Close Date & Time

05 NOV 2020 12:33

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

05 NOV 2020 17:44

PC Open Date & Time

05 NOV 2020 13:28

PC Close Date & Time

06 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	06 NOV 2020 15:37
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	07 NOV 2020 17:29
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	08 NOV 2020 21:37
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 NOV 2020 20:09

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 NOV 2020 05:07

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 NOV 2020 17:43
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

No

Yes

PC Time stamp	05 NOV 2020 10:27
PC Open Date & Time	05 NOV 2020 10:03
PC Close Date & Time	05 NOV 2020 12:33

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

No
Yes

PC Time stamp	05 NOV 2020 17:44
PC Open Date & Time	05 NOV 2020 13:28
PC Close Date & Time	06 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	06 NOV 2020 15:37
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	07 NOV 2020 17:29
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	08 NOV 2020 21:36
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	09 NOV 2020 20:09
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

	Yes <input type="checkbox"/>
PC Time stamp	11 NOV 2020 05:07
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

Yes

PC Time stamp	11 NOV 2020 17:43
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3792090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments CALLED PT FOR DAY 36
SAFETY FOLLOW UP PHONE
CALL. NO RING, JUST GOT A
HIGH PITCHED BEEP.

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 NOV 2020

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

Comments SAFETY FOLLOW UP PHONE
CALL . LEFT A VOICE MAIL
If Contact Not Made, please provide Comments AND ASKED HIM TO CALL ME
BACK.

US3792090

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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 VOICE MAIL AND
ASKED HIM TO CALL ME BACK

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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	VISIT3

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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>)	11:17 (24 HR)
Vital Signs Date and Time (derived)	3 DEC 2020 11:17
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>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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.

US3792090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 3 DEC 2020

Collection time (*00:00-23:59*) 11:23 (24 HR)

Collection date and time (derived) 3 DEC 2020 11:23

US3792090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 05 DEC 2020 10:07:41

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 DEC 2020 15:08:06
Patient Cloud Open Date & Time	11 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	115 of 2456

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 DEC 2020 12:47:43
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 29 DEC 2020 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 89

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 96

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

No

Yes

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

No

Yes

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

Date and time of submission 08 JAN 2021 07:06:21

Patient Cloud Open Date & Time 08 JAN 2021 00:01

Patient Cloud Close Date & Time 12 JAN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 JAN 2021 00:01:20
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 26 JAN 2021 14:29:25

Patient Cloud Open Date & Time 22 JAN 2021 00:01

Patient Cloud Close Date & Time 26 JAN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 JAN 2021 00:01:44
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 131

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 <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	19 FEB 2021 00:01:24
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 FEB 2021 11:05:52
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 06 MAR 2021 11:33:34

Patient Cloud Open Date & Time 05 MAR 2021 00:01

Patient Cloud Close Date & Time 09 MAR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 16 MAR 2021 16:30:22

Patient Cloud Open Date & Time 12 MAR 2021 00:01

Patient Cloud Close Date & Time 16 MAR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 19 MAR 2021 00:01:43

Patient Cloud Open Date & Time 19 MAR 2021 00:01

Patient Cloud Close Date & Time 23 MAR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 28 MAR 2021 12:00:20

Patient Cloud Open Date & Time 26 MAR 2021 00:01

Patient Cloud Close Date & Time 30 MAR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 APR 2021 11:30:12
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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	09 APR 2021 00:01:30
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 APR 2021 00:02:02
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 23 APR 2021 00:01:17

Patient Cloud Open Date & Time 23 APR 2021 00:01

Patient Cloud Close Date & Time 27 APR 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 30 APR 2021 15:29:04

Patient Cloud Open Date & Time 30 APR 2021 00:01

Patient Cloud Close Date & Time 04 MAY 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 215

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 222

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 236

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#) 06 JUL 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 320

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 341

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#) 09 NOV 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 07 DEC 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 28 DEC 2021 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	25 FEB 2022 00:01
Patient Cloud Close Date & Time	01 MAR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	03 MAY 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 600

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 28 JUN 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2022 00:01
Patient Cloud Close Date & Time	01 NOV 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01
Patient Cloud Close Date & Time	22 NOV 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2022 00:01
Patient Cloud Close Date & Time	29 NOV 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2022 00:01
Patient Cloud Close Date & Time	06 DEC 2022 23:59

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#) 13 DEC 2022 23:59

US3792090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:51:14

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		28 FEB 2021 11:05:58

US3792090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 22:51:03

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:51:03

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

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 _____

US3792090

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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)	_____

US3792090

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

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.

US3792090

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

Collection time (*00:00-23:59*) _____

Collection date and time (derived) _____

US3792090

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 21:01:36

Generated On: 10 Jun 2021 09:51:14

Date of Contact	14 DEC 2020
Time of Contact	11:00
Date and Time of Contact (derived)	14 DEC 2020 11:00
Type of Contact	Clinic Visit - Scheduled <input type="radio"/> Clinical Visit - Unscheduled <input checked="" type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Symptom Day

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

Cough	None	<input 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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
-

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Symptom Day

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	99 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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 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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	99 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	99 %
---------------	------

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

Temperature	98.7 F
-------------	--------

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

Cough	None	<input type="radio"/>
	Mild	<input 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)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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 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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	98.6 F
-------------	--------

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

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

Shortness of Breath	None	<input 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)

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US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

None
Mild
Moderate
Severe
Not Done

Runny Nose (Rhinorrhea)

None
Mild
Moderate
Severe
Not Done

Nausea

None
Mild
Moderate
Severe
Not Done

Vomiting

None
Mild
Moderate
Severe
Not Done

Diarrhea

None
Mild
Moderate
Severe
Not Done

Sore Throat

None
Mild
Moderate
Severe
Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	98.9 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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

Date	19 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

Date	20 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

Date	21 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

Cough	None	<input type="radio"/>
	Mild	<input 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

Date	22 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	23 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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 24 DEC 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.5 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	25 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	99.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	26 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	99.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	27 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.9 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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Symptom Day

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	28 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 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" 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"/>

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

	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	29 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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"/>

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US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Date of Visit 14 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 14 DEC 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

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

Start Date _____

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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 _____

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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 _____

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 21:01:36

Generated On: 10 Jun 2021 09:51:14

[Generate Next COVID-19 Assessment](#)

Yes

No

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 05:44:33

Generated On: 10 Jun 2021 09:51:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 DEC 2020
Day 5	Yes	18 DEC 2020
Day 7	Yes	20 DEC 2020
Day 9	Yes	22 DEC 2020
Day 14	Yes	27 DEC 2020
Day 21	Yes	03 JAN 2021
Day 28	Yes	12 JAN 2021

US3792090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 DEC 2020

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

Folder OID SICKD1

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:13 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 11:13
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	290.5 lb
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>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3792090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3792090

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

14 DEC 2020

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	11:45 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 11:45
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3792090

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

12 JAN 2021

US3792090

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 JAN 2021

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

Folder OID UNBLND_DECIDE

US3792090

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 05:44:33

Generated On: 10 Jun 2021 09:51:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 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>)	19 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

US3792090

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Height	_____
Weight	_____
BMI (xxx.x)	_____

US3792090

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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)	19 JAN 2021
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

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)	19 JAN 2021
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 12:22
Temperature (xxx.x)	98.5 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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.

US3792090

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

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) 19 JAN 2021

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 11:49

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

US3792090

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 19 JAN 2021

Collection time (*00:00-23:59*) 10:32 (24 HR)

Collection date and time (derived) 19 JAN 2021 10:32

US3792090

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 19 JAN 2021

Collection time (*00:00 - 23:59*) 10:37

Collection Date and Time (derived) 19 JAN 2021 10:37

US3792090

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3792090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 FEB 2021

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

Folder OID OLD29

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	13:42 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 13:42
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

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 (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	14:29 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:29
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>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3792090

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

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.

US3792090

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was study treatment given? Yes
No

If No, reason not given

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

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

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

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

What was the treatment time? (00:00-23:59) 13:55 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 13:55

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

US3792090

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:02:07

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:01:38

Generated On: 10 Jun 2021 09:51:14

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3792090

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 MAR 2021

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

Folder OID OLD57

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:11 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 12:11
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3792090

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

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.

US3792090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:01:37

Generated On: 10 Jun 2021 09:51:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	31 MAR 2021
Collection time (<i>00:00-23:59</i>)	12:30 (24 HR)
Collection date and time (derived)	31 MAR 2021 12:30

US3792090

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

AEID	USA-US057-2020-MRNA-1273-P30 1000004
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)	12 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)	29 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	POSITIVE FOR COVID-19
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)	

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

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

Yes

No

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

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

Name of Medication NYQUIL - ACETAMINOPHEN
650MG, DEXTROMETHORPHAN
30MG, DOXYFAMINE
SUCCINATE 12.5MG

Prophylaxis Yes
No

Indication COVID-19 SYMPTOM

Dose per administration 30

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:13:55

Generated On: 10 Jun 2021 09:51:14

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 13 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3792090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 21:01:35

Generated On: 10 Jun 2021 09:51:14

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3792090

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:14

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

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

SAEID	USA-US057-2020-MRNA-1273-P30 1000004
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)	4

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

SAEID	USA-US057-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	18/DEC/2020 15:28
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.	<input checked="" type="checkbox"/> True

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

SAEID	USA-US057-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 08:17
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.	<input checked="" type="checkbox"/> True

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

SAEID	USA-US057-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 14:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 15:01:31

Generated On: 10 Jun 2021 09:51:14

SAEID	USA-US057-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	30/APR/2021 08:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3792090 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3792090

Form: Participant Creation

Generated On: 10 Jun 2021 09:51:14

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:20:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'US3792090'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 18:57:54

US3792090

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:35
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:47:24

US3792090

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:35
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 18:57:56

US3792090

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:03:35
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:47:24

US3792090

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'SCRN'	System	07 Oct 2020 19:47:24

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered (b) (6) 1996'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 18:57:57

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '24'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'YEARS'	System	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '24'	System	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered 'Male (M)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '1'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:15

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'Oct 2020'	System	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '2020'	System	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:49:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:49:43
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:43
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:49:27
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:27

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:05:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 18:57:56

US3792090

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '1'	System	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:06:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:51:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:31
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:49:53

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:20:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:20:09
Data point term sent to Coder	System	07 Oct 2020 21:54:58
User entered 'seasonal allergies'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'un UNK 2001'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'Jan 2001'	System	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '2001'	System	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:54:19

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:20:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:20:10
Data point term sent to Coder	System	07 Oct 2020 21:54:59
User entered 'right knee joint pain'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'un UNK 2018'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'Jan 2018'	System	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '2018'	System	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:54:40

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:01:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:01:20
Data point term sent to Coder	System	07 Oct 2020 21:56:02
User entered 'right ankle joint pain'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'un UNK 2018'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'Jan 2018'	System	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '2018'	System	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:55:04

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:21:39
Data point term sent to Coder	System	07 Oct 2020 21:56:02
User entered 'left shoulder pain'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'un UNK 2017'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:04:52
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'Jan 2017'	System	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '2017'	System	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered empty.	System	07 Oct 2020 21:55:23

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered '12:37'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '7 Oct 2020 12:37'	System	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered '75' in	Norma Frederick (b) (4)	07 Oct 2020 19:51:46
DataPoint set to visible.	(b) (4) System	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered '286.8' lb	Norma Frederick (b) (4)	07 Oct 2020 19:51:46
DataPoint set to visible.	(b) (4) System	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '35.92250'	System	07 Oct 2020 19:51:46
DataPoint set to visible.	System	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'kg/m2'	System	07 Oct 2020 19:51:46
DataPoint set to visible.	System	07 Oct 2020 19:49:47

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'bpm'	System	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'breaths/min'	System	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'mmHg'	System	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:45
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered 'mmHg'	System	07 Oct 2020 19:51:46

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35

US3792090

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35

US3792090

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:07
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:43

US3792090

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:07
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:43

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:02:08
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered '1'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:02:08
User entered '0'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:08:59
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:34

US3792090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:09:21
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:57

US3792090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:09:21
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:57

US3792090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[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 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:09:21
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:52:57

US3792090

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'VISIT1'	System	07 Oct 2020 19:52:57

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 19:32:35

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered '116372'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 19:32:35

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 19:32:35

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

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)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:53:38

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

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)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:53:38

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:53:38

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:53:38

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 19:53:38

US3792090

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:14

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:11:38
User entered 'No (N)'	Norma Frederick (b) (4)	07 Oct 2020 19:53:38
DataPoint set to visible.	(b) (4) System	07 Oct 2020 19:49:43

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '12:37'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '7 Oct 2020 12:37'	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 21:57:15
User entered '98.8' F reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 20:15:42
User entered '98,8' (non-conformant).	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 21:57:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 21:57:15
User entered '64' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:15:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'bpm'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 21:57:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 21:57:15
User entered '14' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:15:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'breaths/min'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 21:57:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 21:57:15
User entered '119' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:15:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'mmHg'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 21:57:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 21:57:15
User entered '80' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 20:15:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'mmHg'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 21:57:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 21:57:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:20
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:15:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '13:29' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '7 Oct 2020 13:29'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '97.9' F reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4)	07 Oct 2020 21:57:15
User entered empty.	(b) (4) Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '61' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'bpm'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'breaths/min'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '112' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'mmHg'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:11
User entered '78' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:15
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'mmHg'	System	07 Oct 2020 21:57:15
User entered empty.	System	07 Oct 2020 20:15:42

US3792090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:57
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:27:40

US3792090

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:57
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:27:40

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered '12:52'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '7 Oct 2020 12:52'	System	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:13:13
User entered 'ONCE'	System	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 20:16:13

US3792090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:26
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:08

US3792090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:26
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:08

US3792090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:26
User entered '12:31'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:08

US3792090

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '7 Oct 2020 12:31'	System	07 Oct 2020 20:31:08

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:33
User entered '7 Oct 2020'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:33
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:33
User entered '12:35'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '7 Oct 2020 12:35'	System	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:33
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:33
User entered empty.	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered empty.	System	07 Oct 2020 20:31:41

US3792090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:43
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:43
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 20:31:49

US3792090

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:43
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '1'	System	07 Oct 2020 20:31:49

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b852353b-7d9e-459a-881d-81367bd996c9'	System	07 Oct 2020 20:30:38
User entered 'Yes (Y)'	System	07 Oct 2020 20:30:38

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:11', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b852353b-7d9e-459a-881d-81367bd996c9'	System	07 Oct 2020 20:30:38
User entered '97.9'	System	07 Oct 2020 20:30:38

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b852353b-7d9e-459a-881d-81367bd996c9'	System	07 Oct 2020 20:30:38
User entered 'No (N)'	System	07 Oct 2020 20:30:38

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b852353b-7d9e-459a-881d-81367bd996c9'	System	07 Oct 2020 20:30:38
User entered '07 Oct 2020 13:30'	System	07 Oct 2020 20:30:38

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 13:12'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 15:42'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:14:49', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7e886c1a-9fec-450a-a27e-ce76395a5daf'	System	08 Oct 2020 02:15:02
User entered 'Yes (Y)'	System	08 Oct 2020 02:15:02

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:14:52', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7e886c1a-9fec-450a-a27e-ce76395a5daf'	System	08 Oct 2020 02:15:02
User entered '98.5'	System	08 Oct 2020 02:15:02

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:14:55', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7e886c1a-9fec-450a-a27e-ce76395a5daf'	System	08 Oct 2020 02:15:02
User entered 'No (N)'	System	08 Oct 2020 02:15:02

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:14:57', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7e886c1a-9fec-450a-a27e-ce76395a5daf'	System	08 Oct 2020 02:15:02
User entered '07 Oct 2020 19:14'	System	08 Oct 2020 02:15:02

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 16:37'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 2'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:43:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bab4779d-855b-44f0-930b-037de01f5208'	System	09 Oct 2020 02:44:25
User entered 'Yes (Y)'	System	09 Oct 2020 02:44:25

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:44:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bab4779d-855b-44f0-930b-037de01f5208'	System	09 Oct 2020 02:44:25
User entered '98.5'	System	09 Oct 2020 02:44:25

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:44:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bab4779d-855b-44f0-930b-037de01f5208'	System	09 Oct 2020 02:44:25
User entered 'No (N)'	System	09 Oct 2020 02:44:25

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:44:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bab4779d-855b-44f0-930b-037de01f5208'	System	09 Oct 2020 02:44:25
User entered '08 Oct 2020 19:44'	System	09 Oct 2020 02:44:25

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 3'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '0d951320-3f64-4163-abb9-b70c1d59d3d9'	System	10 Oct 2020 03:44:01
User entered 'Yes (Y)'	System	10 Oct 2020 03:44:01

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '0d951320-3f64-4163-abb9-b70c1d59d3d9'	System	10 Oct 2020 03:44:01
User entered '98.6'	System	10 Oct 2020 03:44:01

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '0d951320-3f64-4163-abb9-b70c1d59d3d9'	System	10 Oct 2020 03:44:01
User entered 'No (N)'	System	10 Oct 2020 03:44:01

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:59', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '0d951320-3f64-4163-abb9-b70c1d59d3d9'	System	10 Oct 2020 03:44:01
User entered '09 Oct 2020 20:43'	System	10 Oct 2020 03:44:01

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 4'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:21:14', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '288197dd-d197-415c-b9fb-c57e3255b458'	System	11 Oct 2020 04:21:29
User entered 'Yes (Y)'	System	11 Oct 2020 04:21:29

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:21:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '288197dd-d197-415c-b9fb-c57e3255b458'	System	11 Oct 2020 04:21:29
User entered '98.7'	System	11 Oct 2020 04:21:29

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:21:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '288197dd-d197-415c-b9fb-c57e3255b458'	System	11 Oct 2020 04:21:29
User entered 'No (N)'	System	11 Oct 2020 04:21:29

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:21:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '288197dd-d197-415c-b9fb-c57e3255b458'	System	11 Oct 2020 04:21:29
User entered '10 Oct 2020 21:21'	System	11 Oct 2020 04:21:29

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 5'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:09:45', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82d7d3a1-2636-410a-a091-e9dd08148cd5'	System	12 Oct 2020 04:09:58
User entered 'Yes (Y)'	System	12 Oct 2020 04:09:58

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:09:50', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82d7d3a1-2636-410a-a091-e9dd08148cd5'	System	12 Oct 2020 04:09:58
User entered '97.9'	System	12 Oct 2020 04:09:58

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:09:54', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82d7d3a1-2636-410a-a091-e9dd08148cd5'	System	12 Oct 2020 04:09:58
User entered 'No (N)'	System	12 Oct 2020 04:09:58

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:09:56', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82d7d3a1-2636-410a-a091-e9dd08148cd5'	System	12 Oct 2020 04:09:58
User entered '11 Oct 2020 21:09'	System	12 Oct 2020 04:09:58

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 6'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1c3db37c-38c9-4145-8b89-b7b30c9ddd92'	System	13 Oct 2020 04:02:11
User entered 'Yes (Y)'	System	13 Oct 2020 04:02:11

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1c3db37c-38c9-4145-8b89-b7b30c9ddd92'	System	13 Oct 2020 04:02:11
User entered '98.7'	System	13 Oct 2020 04:02:11

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1c3db37c-38c9-4145-8b89-b7b30c9ddd92'	System	13 Oct 2020 04:02:11
User entered 'No (N)'	System	13 Oct 2020 04:02:11

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:07', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1c3db37c-38c9-4145-8b89-b7b30c9ddd92'	System	13 Oct 2020 04:02:11
User entered '12 Oct 2020 21:02'	System	13 Oct 2020 04:02:11

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 7'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:38', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e3fdb60c-3a1e-454f-a533-d57a39950c3a'	System	14 Oct 2020 06:06:56
User entered 'Yes (Y)'	System	14 Oct 2020 06:06:56

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e3fdb60c-3a1e-454f-a533-d57a39950c3a'	System	14 Oct 2020 06:06:56
User entered '98.7'	System	14 Oct 2020 06:06:56

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:49', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e3fdb60c-3a1e-454f-a533-d57a39950c3a'	System	14 Oct 2020 06:06:56
User entered 'No (N)'	System	14 Oct 2020 06:06:56

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e3fdb60c-3a1e-454f-a533-d57a39950c3a'	System	14 Oct 2020 06:06:56
User entered '13 Oct 2020 23:06'	System	14 Oct 2020 06:06:56

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '6d6a078c-7048-476d-b135-221760bb17f9'	System	07 Oct 2020 20:31:06
User entered 'None (1)'	System	07 Oct 2020 20:31:06

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:53', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '6d6a078c-7048-476d-b135-221760bb17f9'	System	07 Oct 2020 20:31:06
User entered 'No (N)'	System	07 Oct 2020 20:31:06

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:56', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '6d6a078c-7048-476d-b135-221760bb17f9'	System	07 Oct 2020 20:31:06
User entered 'No (N)'	System	07 Oct 2020 20:31:06

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:30:59', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '6d6a078c-7048-476d-b135-221760bb17f9'	System	07 Oct 2020 20:31:06
User entered 'None (1)'	System	07 Oct 2020 20:31:06

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '6d6a078c-7048-476d-b135-221760bb17f9'	System	07 Oct 2020 20:31:06
User entered '07 Oct 2020 13:31'	System	07 Oct 2020 20:31:06

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 13:12'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 15:42'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7260b973-66ea-477f-880e-c4ca092a0547'	System	08 Oct 2020 02:15:29
User entered 'None (1)'	System	08 Oct 2020 02:15:29

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7260b973-66ea-477f-880e-c4ca092a0547'	System	08 Oct 2020 02:15:29
User entered 'No (N)'	System	08 Oct 2020 02:15:29

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7260b973-66ea-477f-880e-c4ca092a0547'	System	08 Oct 2020 02:15:29
User entered 'No (N)'	System	08 Oct 2020 02:15:29

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:26', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7260b973-66ea-477f-880e-c4ca092a0547'	System	08 Oct 2020 02:15:29
User entered 'None (1)'	System	08 Oct 2020 02:15:29

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:27', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7260b973-66ea-477f-880e-c4ca092a0547'	System	08 Oct 2020 02:15:29
User entered '07 Oct 2020 19:15'	System	08 Oct 2020 02:15:29

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 16:37'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 2'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ea08c24d-a2fb-4a6c-b1c7-ecff1640be6b'	System	09 Oct 2020 02:42:23
User entered 'None (1)'	System	09 Oct 2020 02:42:23

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:12', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ea08c24d-a2fb-4a6c-b1c7-ecff1640be6b'	System	09 Oct 2020 02:42:23
User entered 'No (N)'	System	09 Oct 2020 02:42:23

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ea08c24d-a2fb-4a6c-b1c7-ecff1640be6b'	System	09 Oct 2020 02:42:23
User entered 'No (N)'	System	09 Oct 2020 02:42:23

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:17', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ea08c24d-a2fb-4a6c-b1c7-ecff1640be6b'	System	09 Oct 2020 02:42:23
User entered 'None (1)'	System	09 Oct 2020 02:42:23

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ea08c24d-a2fb-4a6c-b1c7-ecff1640be6b'	System	09 Oct 2020 02:42:23
User entered '08 Oct 2020 19:42'	System	09 Oct 2020 02:42:23

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 3'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:09', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b9e1e4cc-7185-4f11-87fd-612eced5d661'	System	10 Oct 2020 03:43:18
User entered 'None (1)'	System	10 Oct 2020 03:43:18

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b9e1e4cc-7185-4f11-87fd-612eced5d661'	System	10 Oct 2020 03:43:18
User entered 'No (N)'	System	10 Oct 2020 03:43:18

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:12', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b9e1e4cc-7185-4f11-87fd-612eced5d661'	System	10 Oct 2020 03:43:18
User entered 'No (N)'	System	10 Oct 2020 03:43:18

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:14', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b9e1e4cc-7185-4f11-87fd-612eced5d661'	System	10 Oct 2020 03:43:18
User entered 'None (1)'	System	10 Oct 2020 03:43:18

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b9e1e4cc-7185-4f11-87fd-612eced5d661' User entered '09 Oct 2020 20:43'	System	10 Oct 2020 03:43:18
	System	10 Oct 2020 03:43:18

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 4'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:42', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '23b1fdd6-5681-48d8-be66-8dc8501ef2c8'	System	11 Oct 2020 04:19:50
User entered 'None (1)'	System	11 Oct 2020 04:19:50

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '23b1fdd6-5681-48d8-be66-8dc8501ef2c8'	System	11 Oct 2020 04:19:50
User entered 'No (N)'	System	11 Oct 2020 04:19:50

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '23b1fdd6-5681-48d8-be66-8dc8501ef2c8'	System	11 Oct 2020 04:19:50
User entered 'No (N)'	System	11 Oct 2020 04:19:50

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:46', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '23b1fdd6-5681-48d8-be66-8dc8501ef2c8'	System	11 Oct 2020 04:19:50
User entered 'None (1)'	System	11 Oct 2020 04:19:50

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:47', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '23b1fdd6-5681-48d8-be66-8dc8501ef2c8'	System	11 Oct 2020 04:19:50
User entered '10 Oct 2020 21:19'	System	11 Oct 2020 04:19:50

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 5'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:59', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '287573d2-f54a-4601-9a0e-fac2d952b7f7'	System	12 Oct 2020 04:08:11
User entered 'None (1)'	System	12 Oct 2020 04:08:11

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:08:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '287573d2-f54a-4601-9a0e-fac2d952b7f7'	System	12 Oct 2020 04:08:11
User entered 'No (N)'	System	12 Oct 2020 04:08:11

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:08:03', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '287573d2-f54a-4601-9a0e-fac2d952b7f7'	System	12 Oct 2020 04:08:11
User entered 'No (N)'	System	12 Oct 2020 04:08:11

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:08:05', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '287573d2-f54a-4601-9a0e-fac2d952b7f7'	System	12 Oct 2020 04:08:11
User entered 'None (1)'	System	12 Oct 2020 04:08:11

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:08:07', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '287573d2-f54a-4601-9a0e-fac2d952b7f7'	System	12 Oct 2020 04:08:11
User entered '11 Oct 2020 21:08'	System	12 Oct 2020 04:08:11

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 6'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'da3b344e-286a-483c-b2c1-f69b5d7d83d3'	System	13 Oct 2020 04:02:19
User entered 'None (1)'	System	13 Oct 2020 04:02:19

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:11', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'da3b344e-286a-483c-b2c1-f69b5d7d83d3'	System	13 Oct 2020 04:02:19
User entered 'No (N)'	System	13 Oct 2020 04:02:19

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:12', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'da3b344e-286a-483c-b2c1-f69b5d7d83d3'	System	13 Oct 2020 04:02:19
User entered 'No (N)'	System	13 Oct 2020 04:02:19

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'da3b344e-286a-483c-b2c1-f69b5d7d83d3'	System	13 Oct 2020 04:02:19
User entered 'None (1)'	System	13 Oct 2020 04:02:19

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'da3b344e-286a-483c-b2c1-f69b5d7d83d3'	System	13 Oct 2020 04:02:19
User entered '12 Oct 2020 21:02'	System	13 Oct 2020 04:02:19

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 7'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:27', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '361b1a81-8980-43e7-b917-32313b50247e'	System	14 Oct 2020 06:06:39
User entered 'None (1)'	System	14 Oct 2020 06:06:39

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '361b1a81-8980-43e7-b917-32313b50247e'	System	14 Oct 2020 06:06:39
User entered 'No (N)'	System	14 Oct 2020 06:06:39

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:30', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '361b1a81-8980-43e7-b917-32313b50247e'	System	14 Oct 2020 06:06:39
User entered 'No (N)'	System	14 Oct 2020 06:06:39

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '361b1a81-8980-43e7-b917-32313b50247e'	System	14 Oct 2020 06:06:39
User entered 'None (1)'	System	14 Oct 2020 06:06:39

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:34', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '361b1a81-8980-43e7-b917-32313b50247e' User entered '13 Oct 2020 23:06'	System	14 Oct 2020 06:06:39
	System	14 Oct 2020 06:06:39

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:07', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:09', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:11', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'None (0)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered 'No (N)'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T13:31:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '73abf47e-7847-4c4c-9ce3-2ac0dc30443b'	System	07 Oct 2020 20:31:20
User entered '07 Oct 2020 13:31'	System	07 Oct 2020 20:31:20

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 13:12'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 15:42'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:33', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:37', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:55', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:15:57', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'None (0)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:16:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd'	System	08 Oct 2020 02:16:06
User entered 'No (N)'	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-07T19:16:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '3838f139-3298-4959-9a25-5c24270c1acd' User entered '07 Oct 2020 19:16'	System	08 Oct 2020 02:16:06
	System	08 Oct 2020 02:16:06

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Oct 2020 16:37'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 2'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:26', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:28', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'None (0)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:33', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered 'No (N)'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-08T19:42:36', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '16b9dc52-b876-4f8c-abdd-6402c3d371a0'	System	09 Oct 2020 02:42:39
User entered '08 Oct 2020 19:42'	System	09 Oct 2020 02:42:39

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 3'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:42:53', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:42:55', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:42:57', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:42:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:02', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'None (0)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered 'No (N)'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-09T20:43:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e87ec542-9dd4-48a4-9713-ffef26ba0451'	System	10 Oct 2020 03:43:10
User entered '09 Oct 2020 20:43'	System	10 Oct 2020 03:43:10

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 4'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:33', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:36', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:37', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'None (0)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:38', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered 'No (N)'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-10T21:19:39', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'adf450e0-e4ba-4b89-a913-a5f43fa3184c'	System	11 Oct 2020 04:19:44
User entered '10 Oct 2020 21:19'	System	11 Oct 2020 04:19:44

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 5'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:48', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:49', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:50', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:52', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:53', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'None (0)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:54', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered 'No (N)'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-11T21:07:56', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7a4c8d59-a9ca-489e-b27d-cb46de21f81c'	System	12 Oct 2020 04:07:58
User entered '11 Oct 2020 21:07'	System	12 Oct 2020 04:07:58

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 6'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:19', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:21', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dffb47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dffb47'	System	13 Oct 2020 04:02:32
User entered 'None (0)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:26', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered 'No (N)'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-12T21:02:28', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c0f8ec96-fb5d-4bb3-8b8e-4d5bd0dff47'	System	13 Oct 2020 04:02:32
User entered '12 Oct 2020 21:02'	System	13 Oct 2020 04:02:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	07 Oct 2020 20:16:13
User entered 'Day 7'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:14', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:19', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'None (0)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered 'No (N)'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-10-13T23:06:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e4ad07d7-b3c1-4571-828f-7d0cab568480'	System	14 Oct 2020 06:06:32
User entered '13 Oct 2020 23:06'	System	14 Oct 2020 06:06:32

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:16:13

US3792090

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:16:13

US3792090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:32
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	14 Oct 2020 17:40:38

US3792090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:32
User entered '14 Oct 2020'	Ann Marie Milliken (b) (4)	14 Oct 2020 17:40:38

US3792090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:32
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	14 Oct 2020 17:40:38

US3792090

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:32
User entered empty.	Ann Marie Milliken (b) (4)	14 Oct 2020 17:40:38

US3792090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:39
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	14 Oct 2020 17:40:49

US3792090

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '1'	System	14 Oct 2020 17:40:49

US3792090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:50
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	21 Oct 2020 19:37:25

US3792090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:50
User entered '21 Oct 2020'	Ann Marie Milliken (b) (4)	21 Oct 2020 19:37:25

US3792090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:50
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	21 Oct 2020 19:37:25

US3792090

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:55
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:01:50
User entered empty.	Ann Marie Milliken (b) (4)	21 Oct 2020 19:37:25

US3792090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:00
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	21 Oct 2020 19:37:31

US3792090

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:50:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:35:25
User entered '1'	System	21 Oct 2020 19:37:31

US3792090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:08
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	28 Oct 2020 18:52:08

US3792090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:08
User entered '28 Oct 2020'	Ann Marie Milliken (b) (4)	28 Oct 2020 18:52:08

US3792090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:08
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	28 Oct 2020 18:52:08

US3792090

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:08
User entered empty.	Ann Marie Milliken (b) (4)	28 Oct 2020 18:52:08

US3792090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:02:17
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	28 Oct 2020 18:52:14

US3792090

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:55:35
User entered '1'	System	28 Oct 2020 18:52:14

US3792090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:12
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 16:59:25
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:12
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 16:59:25
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	05 Nov 2020 16:59:25
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'VISIT2'	System	05 Nov 2020 16:59:25

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '09:18'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '5 Nov 2020 09:18'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '97.6' F	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '61'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'bpm'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '16'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'breaths/min'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '115'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '77'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '10:26'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '5 Nov 2020 10:26'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '98.1' F	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '66'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'bpm'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '16'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'breaths/min'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '123'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:16
User entered '82'	Norma Frederick (b) (4)	05 Nov 2020 17:36:07
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	05 Nov 2020 17:36:07

US3792090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:46
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 16:59:37
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:46
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 16:59:37
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:50
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:08
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:50
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 17:00:08
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:50
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 17:00:08
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'MRNA-1273 OR PLACEBO'	System	05 Nov 2020 17:00:08

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:50
	(b) (4)	
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 17:00:08
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:50
	(b) (4)	
User entered '09:43'	Norma Frederick (b) (4)	05 Nov 2020 17:00:08
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '5 Nov 2020 09:43'	System	05 Nov 2020 17:00:08

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:28:50
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 17:00:08

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:28:50
User entered 'ONCE'	System	05 Nov 2020 17:00:08

US3792090

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'INTRAMUSCULAR'	System	05 Nov 2020 17:00:08

US3792090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:27
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:35
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:31:27
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:50:45
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' answered with 'Subject US3792090 V2 was collected on 05NOV2020 and is correct in GCL.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:41:39
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:56:41
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 17:00:35

US3792090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:27
User entered '09:26'	Norma Frederick (b) (4)	05 Nov 2020 17:00:35
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '5 Nov 2020 09:26'	System	05 Nov 2020 17:00:35

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:52
User entered '5 Nov 2020'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:52
User entered '09:30'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '5 Nov 2020 09:30'	System	05 Nov 2020 17:00:56

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
	(b) (4)	
	(b) (4)	
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:31:52
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:52
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 17:00:56
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered empty.	System	05 Nov 2020 17:00:56

US3792090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:31:58
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 17:01:01
	(b) (4)	

US3792090

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '1'	System	05 Nov 2020 17:01:01

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:39', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82f04f50-2c7a-4f21-b730-ad1be42a3413'	System	05 Nov 2020 17:26:50
User entered 'Yes (Y)'	System	05 Nov 2020 17:26:50

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82f04f50-2c7a-4f21-b730-ad1be42a3413'	System	05 Nov 2020 17:26:50
User entered '98.1'	System	05 Nov 2020 17:26:50

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:45', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82f04f50-2c7a-4f21-b730-ad1be42a3413'	System	05 Nov 2020 17:26:50
User entered 'No (N)'	System	05 Nov 2020 17:26:50

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:47', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '82f04f50-2c7a-4f21-b730-ad1be42a3413'	System	05 Nov 2020 17:26:50
User entered '05 Nov 2020 10:26'	System	05 Nov 2020 17:26:50

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 10:03'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 12:33'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T22:50:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '07fa427d-b100-45b8-bf80-c81655b76498'	System	06 Nov 2020 05:51:08
User entered 'Yes (Y)'	System	06 Nov 2020 05:51:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T22:51:02', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '07fa427d-b100-45b8-bf80-c81655b76498'	System	06 Nov 2020 05:51:08
User entered '98.1'	System	06 Nov 2020 05:51:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T22:51:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '07fa427d-b100-45b8-bf80-c81655b76498'	System	06 Nov 2020 05:51:08
User entered 'No (N)'	System	06 Nov 2020 05:51:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T22:51:05', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '07fa427d-b100-45b8-bf80-c81655b76498'	System	06 Nov 2020 05:51:08
User entered '05 Nov 2020 22:51'	System	06 Nov 2020 05:51:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 13:28'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 2'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:36:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c271a1fd-739e-44fa-815c-2c4c0ef6da2e'	System	06 Nov 2020 22:37:06
User entered 'Yes (Y)'	System	06 Nov 2020 22:37:06

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:36:48', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c271a1fd-739e-44fa-815c-2c4c0ef6da2e'	System	06 Nov 2020 22:37:06
User entered '98.5'	System	06 Nov 2020 22:37:06

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:36:50', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c271a1fd-739e-44fa-815c-2c4c0ef6da2e'	System	06 Nov 2020 22:37:06
User entered 'No (N)'	System	06 Nov 2020 22:37:06

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:36:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'c271a1fd-739e-44fa-815c-2c4c0ef6da2e'	System	06 Nov 2020 22:37:06
User entered '06 Nov 2020 15:36'	System	06 Nov 2020 22:37:06

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 3'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:52', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8405cf74-a08a-449d-99c8-3c59e36e5348'	System	08 Nov 2020 00:30:37
User entered 'Yes (Y)'	System	08 Nov 2020 00:30:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:30:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8405cf74-a08a-449d-99c8-3c59e36e5348'	System	08 Nov 2020 00:30:37
User entered '98.3'	System	08 Nov 2020 00:30:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:30:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8405cf74-a08a-449d-99c8-3c59e36e5348'	System	08 Nov 2020 00:30:37
User entered 'No (N)'	System	08 Nov 2020 00:30:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:30:34', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8405cf74-a08a-449d-99c8-3c59e36e5348'	System	08 Nov 2020 00:30:37
User entered '07 Nov 2020 17:30'	System	08 Nov 2020 00:30:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 4'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:38:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '88a00e4d-6981-4ed3-ad1d-391aa8dbff55'	System	09 Nov 2020 04:38:37
User entered 'Yes (Y)'	System	09 Nov 2020 04:38:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:38:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '88a00e4d-6981-4ed3-ad1d-391aa8dbff55'	System	09 Nov 2020 04:38:37
User entered '98.6'	System	09 Nov 2020 04:38:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:38:34', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '88a00e4d-6981-4ed3-ad1d-391aa8dbff55'	System	09 Nov 2020 04:38:37
User entered 'No (N)'	System	09 Nov 2020 04:38:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:38:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '88a00e4d-6981-4ed3-ad1d-391aa8dbff55'	System	09 Nov 2020 04:38:37
User entered '08 Nov 2020 21:38'	System	09 Nov 2020 04:38:37

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 5'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:08:56', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '507b8825-6431-41d2-8868-86ed92df45bf'	System	10 Nov 2020 03:09:10
User entered 'Yes (Y)'	System	10 Nov 2020 03:09:10

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '507b8825-6431-41d2-8868-86ed92df45bf' User entered '98.6'	System	10 Nov 2020 03:09:10
	System	10 Nov 2020 03:09:10

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:03', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '507b8825-6431-41d2-8868-86ed92df45bf'	System	10 Nov 2020 03:09:10
User entered 'No (N)'	System	10 Nov 2020 03:09:10

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:05', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '507b8825-6431-41d2-8868-86ed92df45bf' User entered '09 Nov 2020 20:09'	System	10 Nov 2020 03:09:10
	System	10 Nov 2020 03:09:10

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 6'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '398dd6a2-2b1c-432f-a26a-52d95ad1ecdf'	System	11 Nov 2020 12:07:31
User entered 'Yes (Y)'	System	11 Nov 2020 12:07:31

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '398dd6a2-2b1c-432f-a26a-52d95ad1ecdf' User entered '98.6'	System	11 Nov 2020 12:07:31
	System	11 Nov 2020 12:07:31

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '398dd6a2-2b1c-432f-a26a-52d95ad1ecdf'	System	11 Nov 2020 12:07:31
User entered 'No (N)'	System	11 Nov 2020 12:07:31

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:25', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '398dd6a2-2b1c-432f-a26a-52d95ad1ecdf' User entered '11 Nov 2020 05:07'	System	11 Nov 2020 12:07:31
	System	11 Nov 2020 12:07:31

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 7'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:42:50', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a26ee1fb-1a6d-49d0-90c8-d726178de0eb'	System	12 Nov 2020 00:43:01
User entered 'Yes (Y)'	System	12 Nov 2020 00:43:01

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:42:54', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a26ee1fb-1a6d-49d0-90c8-d726178de0eb'	System	12 Nov 2020 00:43:01
User entered '98.6'	System	12 Nov 2020 00:43:01

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:42:56', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a26ee1fb-1a6d-49d0-90c8-d726178de0eb'	System	12 Nov 2020 00:43:01
User entered 'No (N)'	System	12 Nov 2020 00:43:01

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:42:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a26ee1fb-1a6d-49d0-90c8-d726178de0eb'	System	12 Nov 2020 00:43:01
User entered '11 Nov 2020 17:42'	System	12 Nov 2020 00:43:01

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:49', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '04d6d41f-a3b7-4356-8f8c-15f9a5cd05aa'	System	05 Nov 2020 17:27:02
User entered 'None (1)'	System	05 Nov 2020 17:27:02

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:52', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '04d6d41f-a3b7-4356-8f8c-15f9a5cd05aa'	System	05 Nov 2020 17:27:02
User entered 'No (N)'	System	05 Nov 2020 17:27:02

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:54', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '04d6d41f-a3b7-4356-8f8c-15f9a5cd05aa'	System	05 Nov 2020 17:27:02
User entered 'No (N)'	System	05 Nov 2020 17:27:02

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:55', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '04d6d41f-a3b7-4356-8f8c-15f9a5cd05aa'	System	05 Nov 2020 17:27:02
User entered 'None (1)'	System	05 Nov 2020 17:27:02

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:26:57', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '04d6d41f-a3b7-4356-8f8c-15f9a5cd05aa'	System	05 Nov 2020 17:27:02
User entered '05 Nov 2020 10:26'	System	05 Nov 2020 17:27:02

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 10:03'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 12:33'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b23a7b7e-28e3-4e15-93c8-482f9cc22b52'	System	06 Nov 2020 00:44:37
User entered 'None (1)'	System	06 Nov 2020 00:44:37

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:26', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b23a7b7e-28e3-4e15-93c8-482f9cc22b52'	System	06 Nov 2020 00:44:37
User entered 'No (N)'	System	06 Nov 2020 00:44:37

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:28', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b23a7b7e-28e3-4e15-93c8-482f9cc22b52'	System	06 Nov 2020 00:44:37
User entered 'No (N)'	System	06 Nov 2020 00:44:37

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:30', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b23a7b7e-28e3-4e15-93c8-482f9cc22b52'	System	06 Nov 2020 00:44:37
User entered 'None (1)'	System	06 Nov 2020 00:44:37

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b23a7b7e-28e3-4e15-93c8-482f9cc22b52'	System	06 Nov 2020 00:44:37
User entered '05 Nov 2020 17:44'	System	06 Nov 2020 00:44:37

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 13:28'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 2'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e922bf24-e954-4c4b-b8a4-c55c67cb174f'	System	06 Nov 2020 22:37:22
User entered 'None (1)'	System	06 Nov 2020 22:37:22

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:03', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e922bf24-e954-4c4b-b8a4-c55c67cb174f'	System	06 Nov 2020 22:37:22
User entered 'No (N)'	System	06 Nov 2020 22:37:22

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:05', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e922bf24-e954-4c4b-b8a4-c55c67cb174f'	System	06 Nov 2020 22:37:22
User entered 'No (N)'	System	06 Nov 2020 22:37:22

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e922bf24-e954-4c4b-b8a4-c55c67cb174f'	System	06 Nov 2020 22:37:22
User entered 'None (1)'	System	06 Nov 2020 22:37:22

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:08', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e922bf24-e954-4c4b-b8a4-c55c67cb174f' User entered '06 Nov 2020 15:37'	System	06 Nov 2020 22:37:22
	System	06 Nov 2020 22:37:22

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 3'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'dc27bc87-bcd0-417d-8817-ea8283393c43'	System	08 Nov 2020 00:29:20
User entered 'None (1)'	System	08 Nov 2020 00:29:20

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'dc27bc87-bcd0-417d-8817-ea8283393c43'	System	08 Nov 2020 00:29:20
User entered 'No (N)'	System	08 Nov 2020 00:29:20

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'dc27bc87-bcd0-417d-8817-ea8283393c43'	System	08 Nov 2020 00:29:20
User entered 'No (N)'	System	08 Nov 2020 00:29:20

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'dc27bc87-bcd0-417d-8817-ea8283393c43'	System	08 Nov 2020 00:29:20
User entered 'None (1)'	System	08 Nov 2020 00:29:20

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'dc27bc87-bcd0-417d-8817-ea8283393c43'	System	08 Nov 2020 00:29:20
User entered '07 Nov 2020 17:29'	System	08 Nov 2020 00:29:20

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 4'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:57', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08f041a6-3550-4c44-b4f2-dbf7ca6a1dff'	System	09 Nov 2020 04:37:05
User entered 'None (1)'	System	09 Nov 2020 04:37:05

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08f041a6-3550-4c44-b4f2-dbf7ca6a1dff'	System	09 Nov 2020 04:37:05
User entered 'No (N)'	System	09 Nov 2020 04:37:05

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:59', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08f041a6-3550-4c44-b4f2-dbf7ca6a1dff'	System	09 Nov 2020 04:37:05
User entered 'No (N)'	System	09 Nov 2020 04:37:05

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:37:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08f041a6-3550-4c44-b4f2-dbf7ca6a1dff'	System	09 Nov 2020 04:37:05
User entered 'None (1)'	System	09 Nov 2020 04:37:05

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:37:02', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08f041a6-3550-4c44-b4f2-dbf7ca6a1dff' User entered '08 Nov 2020 21:37'	System	09 Nov 2020 04:37:05
	System	09 Nov 2020 04:37:05

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 5'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:08', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '989902cb-d948-4e4b-8c67-ece891050717'	System	10 Nov 2020 03:09:16
User entered 'None (1)'	System	10 Nov 2020 03:09:16

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:09', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '989902cb-d948-4e4b-8c67-ece891050717'	System	10 Nov 2020 03:09:16
User entered 'No (N)'	System	10 Nov 2020 03:09:16

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '989902cb-d948-4e4b-8c67-ece891050717'	System	10 Nov 2020 03:09:16
User entered 'No (N)'	System	10 Nov 2020 03:09:16

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:11', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '989902cb-d948-4e4b-8c67-ece891050717'	System	10 Nov 2020 03:09:16
User entered 'None (1)'	System	10 Nov 2020 03:09:16

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '989902cb-d948-4e4b-8c67-ece891050717'	System	10 Nov 2020 03:09:16
User entered '09 Nov 2020 20:09'	System	10 Nov 2020 03:09:16

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 6'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'f1ce0af0-de6b-4316-a629-07a1ec890aa0'	System	11 Nov 2020 12:07:39
User entered 'None (1)'	System	11 Nov 2020 12:07:39

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:30', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'f1ce0af0-de6b-4316-a629-07a1ec890aa0'	System	11 Nov 2020 12:07:39
User entered 'No (N)'	System	11 Nov 2020 12:07:39

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'f1ce0af0-de6b-4316-a629-07a1ec890aa0'	System	11 Nov 2020 12:07:39
User entered 'No (N)'	System	11 Nov 2020 12:07:39

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:34', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'f1ce0af0-de6b-4316-a629-07a1ec890aa0'	System	11 Nov 2020 12:07:39
User entered 'None (1)'	System	11 Nov 2020 12:07:39

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:37', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'f1ce0af0-de6b-4316-a629-07a1ec890aa0'	System	11 Nov 2020 12:07:39
User entered '11 Nov 2020 05:07'	System	11 Nov 2020 12:07:39

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 7'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4c8049-19b8-4ed4-a9d9-25507e7f6dd8'	System	12 Nov 2020 00:43:08
User entered 'None (1)'	System	12 Nov 2020 00:43:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4c8049-19b8-4ed4-a9d9-25507e7f6dd8'	System	12 Nov 2020 00:43:08
User entered 'No (N)'	System	12 Nov 2020 00:43:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:02', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4c8049-19b8-4ed4-a9d9-25507e7f6dd8'	System	12 Nov 2020 00:43:08
User entered 'No (N)'	System	12 Nov 2020 00:43:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:03', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4c8049-19b8-4ed4-a9d9-25507e7f6dd8'	System	12 Nov 2020 00:43:08
User entered 'None (1)'	System	12 Nov 2020 00:43:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4c8049-19b8-4ed4-a9d9-25507e7f6dd8'	System	12 Nov 2020 00:43:08
User entered '11 Nov 2020 17:43'	System	12 Nov 2020 00:43:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:02', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:05', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'None (0)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered 'No (N)'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T10:27:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '24445dc6-3981-43f4-9232-463ed3a06bc5'	System	05 Nov 2020 17:27:26
User entered '05 Nov 2020 10:27'	System	05 Nov 2020 17:27:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 10:03'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 12:33'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:37', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:38', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:39', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:40', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'None (0)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered 'No (N)'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-05T17:44:46', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6644056-27b3-4062-b0a9-22fc909e0e48'	System	06 Nov 2020 00:44:49
User entered '05 Nov 2020 17:44'	System	06 Nov 2020 00:44:49

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '05 Nov 2020 13:28'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 2'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:21', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'No interference with activity (1)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'No interference with activity (1)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'No interference with activity (1)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'None (0)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:39', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'None (0)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'None (0)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered 'No (N)'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-06T15:37:46', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '7c60a603-0b21-4bb7-b512-c60c581cbde3'	System	06 Nov 2020 22:37:52
User entered '06 Nov 2020 15:37'	System	06 Nov 2020 22:37:52

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 3'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:42', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'None (0)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:47', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered 'No (N)'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-07T17:29:49', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1ada5bd5-982c-4312-a824-1696652caa96'	System	08 Nov 2020 00:29:54
User entered '07 Nov 2020 17:29'	System	08 Nov 2020 00:29:54

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 4'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:29', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1'	System	09 Nov 2020 04:36:39
User entered 'None (0)'	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:30', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1'	System	09 Nov 2020 04:36:39
User entered 'None (0)'	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1' User entered 'None (0)'	System	09 Nov 2020 04:36:39
	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:31', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1' User entered 'None (0)'	System	09 Nov 2020 04:36:39
	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:33', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1'	System	09 Nov 2020 04:36:39
User entered 'None (0)'	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:33', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1'	System	09 Nov 2020 04:36:39
User entered 'None (0)'	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:34', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1'	System	09 Nov 2020 04:36:39
User entered 'No (N)'	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-08T21:36:36', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ece9f159-efd1-4b63-9fa4-d302869ef1b1' User entered '08 Nov 2020 21:36'	System	09 Nov 2020 04:36:39
	System	09 Nov 2020 04:36:39

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 5'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:16', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:17', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:18', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:19', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'None (0)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:21', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered 'No (N)'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-09T20:09:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '512301b8-2307-47b1-9c8f-9a3989d21fc5'	System	10 Nov 2020 03:09:26
User entered '09 Nov 2020 20:09'	System	10 Nov 2020 03:09:26

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 6'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:45', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:46', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:48', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:50', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'None (0)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:51', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered 'No (N)'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T05:07:53', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e484fdf2-38e4-46dc-9532-2bc160706a62'	System	11 Nov 2020 12:07:57
User entered '11 Nov 2020 05:07'	System	11 Nov 2020 12:07:57

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
Data entry locked.	System	05 Nov 2020 17:00:08
User entered 'Day 7'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:07', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:08', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:09', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:10', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:11', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:12', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'None (0)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

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 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:13', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde'	System	12 Nov 2020 00:43:20
User entered 'No (N)'	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-11-11T17:43:15', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '327f20dc-6fbf-44a8-b175-6fe9e7a40bde' User entered '11 Nov 2020 17:43'	System	12 Nov 2020 00:43:20
	System	12 Nov 2020 00:43:20

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 17:00:08

US3792090

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:09
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 17:00:08

US3792090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:45
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:07:48
	(b) (4)	

US3792090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:45
User entered '12 Nov 2020'	Norma Frederick (b) (4)	03 Dec 2020 19:07:48
	(b) (4)	

US3792090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:45
User entered 'Contact Not Made (CONTACT NOT MADE)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:07:48

US3792090

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:45
User entered 'CALLED PT FOR DAY 36 SAFETY FOLLOW UP PHONE CALL. NO RING, JUST GOT A HIGH PITCHED BEEP.'	Norma Frederick (b) (4)	03 Dec 2020 19:07:48

US3792090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:07:54
	(b) (4)	

US3792090

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '1'	System	03 Dec 2020 19:07:54

US3792090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:59
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:09:05
	(b) (4)	

US3792090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:59
User entered '19 Nov 2020'	Norma Frederick (b) (4)	03 Dec 2020 19:09:05
	(b) (4)	

US3792090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:59
User entered 'Contact Not Made (CONTACT NOT MADE)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:09:05

US3792090

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:06:59
User entered 'SAFETY FOLLOW UP PHONE CALL . LEFT A VOICE MAIL AND ASKED HIM TO CALL ME BACK.'	Norma Frederick (b) (4)	03 Dec 2020 19:09:05

US3792090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:07:05
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:09:10
	(b) (4)	

US3792090

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '1'	System	03 Dec 2020 19:09:10

US3792090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:08:12
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:11:19
	(b) (4)	

US3792090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
	(b) (4)	
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 09:47:01
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD filed in source for call made 1 day too early due to Holiday ' (Site from System).	Norma Frederick (b) (4)	11 Mar 2021 17:02:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:08:12
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Dec 2020 19:11:19
User entered '25 Nov 2020'	Norma Frederick (b) (4)	03 Dec 2020 19:11:19
	(b) (4)	

US3792090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:08:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:11:19

US3792090

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:08:12
User entered 'LEFT A VOICE MAIL AND ASKED HIM TO CALL ME BACK'	Norma Frederick (b) (4)	03 Dec 2020 19:11:19
	(b) (4)	

US3792090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:08:28
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:11:25
	(b) (4)	

US3792090

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '1'	System	03 Dec 2020 19:11:25

US3792090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:17:03
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:11:35

US3792090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:17:03
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:11:35

US3792090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:17:03
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:11:35

US3792090

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'VISIT3'	System	03 Dec 2020 19:11:35

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '11:17'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '3 Dec 2020 11:17'	System	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '98.0' F	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '67'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'bpm'	System	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '16'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'breaths/min'	System	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '121'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:23
User entered '88'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered 'mmHg'	System	03 Dec 2020 19:12:58

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10

US3792090

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10

US3792090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:29
User entered 'No (N)'	Norma Frederick (b) (4)	03 Dec 2020 19:13:01
	(b) (4)	

US3792090

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:13:01

US3792090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	03 Dec 2020 19:13:16
	(b) (4)	

US3792090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:51
User entered '3 Dec 2020'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:13:16

US3792090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:51
User entered '11:23'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:13:16

US3792090

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '3 Dec 2020 11:23'	System	03 Dec 2020 19:13:16

US3792090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:18:58
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Dec 2020 19:13:22

US3792090

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:37:10
User entered '1'	System	03 Dec 2020 19:13:22

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2020-12-05T10:07:38', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ae6d91b2-9cd5-489c-addf-1d50453a21e3'	System	05 Dec 2020 17:07:44
User entered 'No (N)'	System	05 Dec 2020 17:07:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2020-12-05T10:07:40', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ae6d91b2-9cd5-489c-addf-1d50453a21e3'	System	05 Dec 2020 17:07:44
User entered 'No (N)'	System	05 Dec 2020 17:07:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-05T10:07:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ae6d91b2-9cd5-489c-addf-1d50453a21e3'	System	05 Dec 2020 17:07:44
User entered '05 Dec 2020 10:07:41'	System	05 Dec 2020 17:07:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2020-12-12T15:07:35', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'Yes (Y)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2020-12-12T15:07:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'Yes (Y)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:46', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:54', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'Yes (Y)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a' User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '1'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:07:58', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '0'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:08:01', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:08:04', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered 'No (N)'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-12T15:08:06', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'a5111c47-ca85-4945-bc1b-044fbe7af03a'	System	12 Dec 2020 22:08:15
User entered '12 Dec 2020 15:08:06'	System	12 Dec 2020 22:08:15

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2020-12-20T12:47:26', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered 'Yes (Y)'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2020-12-20T12:47:30', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered 'Yes (Y)'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-20T12:47:32', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-20T12:47:36', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered 'No (N)'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-20T12:47:41', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered 'No (N)'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2020-12-20T12:47:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'cb4aa8d3-ee19-4a38-997e-fd88ea5b26f5'	System	20 Dec 2020 19:47:51
User entered '20 Dec 2020 12:47:43'	System	20 Dec 2020 19:47:51

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-01-08T07:06:17', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8f289209-59b8-4bed-b25b-0b4d60878f86'	System	08 Jan 2021 14:06:23
User entered 'No (N)'	System	08 Jan 2021 14:06:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-01-08T07:06:19', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8f289209-59b8-4bed-b25b-0b4d60878f86'	System	08 Jan 2021 14:06:23
User entered 'No (N)'	System	08 Jan 2021 14:06:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-01-08T07:06:21', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '8f289209-59b8-4bed-b25b-0b4d60878f86'	System	08 Jan 2021 14:06:23
User entered '08 Jan 2021 07:06:21'	System	08 Jan 2021 14:06:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-01-15T00:01:17', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ec43c6f0-467b-4a25-aa7b-d0ba13654da6'	System	15 Jan 2021 07:01:23
User entered 'No (N)'	System	15 Jan 2021 07:01:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-01-15T00:01:19', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ec43c6f0-467b-4a25-aa7b-d0ba13654da6'	System	15 Jan 2021 07:01:23
User entered 'No (N)'	System	15 Jan 2021 07:01:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-01-15T00:01:20', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ec43c6f0-467b-4a25-aa7b-d0ba13654da6'	System	15 Jan 2021 07:01:23
User entered '15 Jan 2021 00:01:20'	System	15 Jan 2021 07:01:23

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-01-26T14:29:22', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '301c6a50-4839-4e25-a294-51c7f1c24320'	System	26 Jan 2021 22:00:45
User entered 'No (N)'	System	26 Jan 2021 22:00:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-01-26T14:29:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '301c6a50-4839-4e25-a294-51c7f1c24320'	System	26 Jan 2021 22:00:45
User entered 'No (N)'	System	26 Jan 2021 22:00:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-01-26T14:29:25', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '301c6a50-4839-4e25-a294-51c7f1c24320' User entered '26 Jan 2021 14:29:25'	System	26 Jan 2021 22:00:45
	System	26 Jan 2021 22:00:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-01-29T00:01:42', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e95c02c6-7c97-48ab-a92d-a100fee6629a'	System	29 Jan 2021 07:01:47
User entered 'No (N)'	System	29 Jan 2021 07:01:47

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-01-29T00:01:43', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e95c02c6-7c97-48ab-a92d-a100fee6629a'	System	29 Jan 2021 07:01:47
User entered 'No (N)'	System	29 Jan 2021 07:01:47

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-01-29T00:01:44', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e95c02c6-7c97-48ab-a92d-a100fee6629a' User entered '29 Jan 2021 00:01:44'	System	29 Jan 2021 07:01:47
	System	29 Jan 2021 07:01:47

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-02-19T00:01:21', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '9df2efb9-21aa-4c44-8cb4-74f07b47f14d'	System	19 Feb 2021 07:01:25
User entered 'No (N)'	System	19 Feb 2021 07:01:25

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-02-19T00:01:23', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '9df2efb9-21aa-4c44-8cb4-74f07b47f14d'	System	19 Feb 2021 07:01:25
User entered 'No (N)'	System	19 Feb 2021 07:01:25

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-02-19T00:01:24', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '9df2efb9-21aa-4c44-8cb4-74f07b47f14d'	System	19 Feb 2021 07:01:25
User entered '19 Feb 2021 00:01:24'	System	19 Feb 2021 07:01:25

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-02-28T11:05:48-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6ea3ba4-0100-4fa2-91f1-9746c7f1d293'	System	28 Feb 2021 18:09:44
User entered 'No (N)'	System	28 Feb 2021 18:09:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-02-28T11:05:50-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6ea3ba4-0100-4fa2-91f1-9746c7f1d293'	System	28 Feb 2021 18:09:44
User entered 'No (N)'	System	28 Feb 2021 18:09:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-02-28T11:05:52-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'e6ea3ba4-0100-4fa2-91f1-9746c7f1d293'	System	28 Feb 2021 18:09:44
User entered '28 Feb 2021 11:05:52'	System	28 Feb 2021 18:09:44

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-03-06T11:33:30-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bcbd83b2-62db-4073-82ee-db5517cd410c'	System	06 Mar 2021 18:33:38
User entered 'No (N)'	System	06 Mar 2021 18:33:38

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-03-06T11:33:32-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bcbd83b2-62db-4073-82ee-db5517cd410c'	System	06 Mar 2021 18:33:38
User entered 'No (N)'	System	06 Mar 2021 18:33:38

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-03-06T11:33:34-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'bcbd83b2-62db-4073-82ee-db5517cd410c'	System	06 Mar 2021 18:33:38
User entered '06 Mar 2021 11:33:34'	System	06 Mar 2021 18:33:38

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-03-16T16:30:17-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '34bc72a1-fe19-453e-8200-101ed5727441'	System	16 Mar 2021 23:30:27
User entered 'No (N)'	System	16 Mar 2021 23:30:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-03-16T16:30:19-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '34bc72a1-fe19-453e-8200-101ed5727441'	System	16 Mar 2021 23:30:27
User entered 'No (N)'	System	16 Mar 2021 23:30:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-03-16T16:30:22-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '34bc72a1-fe19-453e-8200-101ed5727441'	System	16 Mar 2021 23:30:27
User entered '16 Mar 2021 16:30:22'	System	16 Mar 2021 23:30:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-03-19T00:01:39-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '2ce587af-162e-495a-aa93-ce90729fc332'	System	19 Mar 2021 07:01:45
User entered 'No (N)'	System	19 Mar 2021 07:01:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-03-19T00:01:41-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '2ce587af-162e-495a-aa93-ce90729fc332'	System	19 Mar 2021 07:01:45
User entered 'No (N)'	System	19 Mar 2021 07:01:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-03-19T00:01:43-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '2ce587af-162e-495a-aa93-ce90729fc332'	System	19 Mar 2021 07:01:45
User entered '19 Mar 2021 00:01:43'	System	19 Mar 2021 07:01:45

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-03-28T12:00:17-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ad625057-e14c-4148-8ea2-9de41580155f' User entered 'No (N)'	System	28 Mar 2021 19:00:27
	System	28 Mar 2021 19:00:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-03-28T12:00:18-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ad625057-e14c-4148-8ea2-9de41580155f'	System	28 Mar 2021 19:00:27
User entered 'No (N)'	System	28 Mar 2021 19:00:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-03-28T12:00:20-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'ad625057-e14c-4148-8ea2-9de41580155f'	System	28 Mar 2021 19:00:27
User entered '28 Mar 2021 12:00:20'	System	28 Mar 2021 19:00:27

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-04-03T11:30:09-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '15f083ef-5c8d-4975-81dd-2c814da4948b'	System	03 Apr 2021 18:30:14
User entered 'No (N)'	System	03 Apr 2021 18:30:14

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-04-03T11:30:10-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '15f083ef-5c8d-4975-81dd-2c814da4948b'	System	03 Apr 2021 18:30:14
User entered 'No (N)'	System	03 Apr 2021 18:30:14

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-04-03T11:30:12-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '15f083ef-5c8d-4975-81dd-2c814da4948b'	System	03 Apr 2021 18:30:14
User entered '03 Apr 2021 11:30:12'	System	03 Apr 2021 18:30:14

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-04-09T00:01:28-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b7911233-77d7-47e8-a4dc-6af0cf3809e5'	System	09 Apr 2021 07:01:35
User entered 'No (N)'	System	09 Apr 2021 07:01:35

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-04-09T00:01:29-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b7911233-77d7-47e8-a4dc-6af0cf3809e5'	System	09 Apr 2021 07:01:35
User entered 'No (N)'	System	09 Apr 2021 07:01:35

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-04-09T00:01:30-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'b7911233-77d7-47e8-a4dc-6af0cf3809e5'	System	09 Apr 2021 07:01:35
User entered '09 Apr 2021 00:01:30'	System	09 Apr 2021 07:01:35

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-04-16T00:01:59-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '02f17daf-e5f0-40eb-a67f-8c098434bff7'	System	16 Apr 2021 07:02:08
User entered 'No (N)'	System	16 Apr 2021 07:02:08

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-04-16T00:02:01-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '02f17daf-e5f0-40eb-a67f-8c098434bff7'	System	16 Apr 2021 07:02:08
User entered 'No (N)'	System	16 Apr 2021 07:02:08

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-04-16T00:02:02-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '02f17daf-e5f0-40eb-a67f-8c098434bff7'	System	16 Apr 2021 07:02:08
User entered '16 Apr 2021 00:02:02'	System	16 Apr 2021 07:02:08

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[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 (72856e911ac1b0d2)', Time: '2021-04-23T00:01:14-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1e6b8626-e3f4-4084-9f4e-1f751de2afe6'	System	23 Apr 2021 07:01:22
User entered 'No (N)'	System	23 Apr 2021 07:01:22

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-04-23T00:01:15-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1e6b8626-e3f4-4084-9f4e-1f751de2afe6'	System	23 Apr 2021 07:01:22
User entered 'No (N)'	System	23 Apr 2021 07:01:22

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-04-23T00:01:17-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '1e6b8626-e3f4-4084-9f4e-1f751de2afe6'	System	23 Apr 2021 07:01:22
User entered '23 Apr 2021 00:01:17'	System	23 Apr 2021 07:01:22

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

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 (72856e911ac1b0d2)', Time: '2021-04-30T15:29:01-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08722e38-d5a3-4b8c-918a-f84583b2b221'	System	30 Apr 2021 22:29:06
User entered 'No (N)'	System	30 Apr 2021 22:29:06

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

Have you been exposed to someone with 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 (72856e911ac1b0d2)', Time: '2021-04-30T15:29:03-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08722e38-d5a3-4b8c-918a-f84583b2b221'	System	30 Apr 2021 22:29:06
User entered 'No (N)'	System	30 Apr 2021 22:29:06

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-04-30T15:29:04-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: '08722e38-d5a3-4b8c-918a-f84583b2b221'	System	30 Apr 2021 22:29:06
User entered '30 Apr 2021 15:29:04'	System	30 Apr 2021 22:29:06

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 11:59:34

US3792090

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:59:34
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 11:59:34

US3792090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:14

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 22:02:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-02-28T11:05:57-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'd012f66d-dc61-4966-9b7b-0e60d148970b'	System	28 Feb 2021 18:09:49
User entered 'No (N)'	System	28 Feb 2021 18:09:49

US3792090

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:02:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72856e911ac1b0d2)', Time: '2021-02-28T11:05:58-07:00', User OID: 'PatientReportedOutcome (US3792090)', ODM File OID: 'd012f66d-dc61-4966-9b7b-0e60d148970b' User entered '28 Feb 2021 11:05:58'	System	28 Feb 2021 18:09:49
	System	28 Feb 2021 18:09:49

US3792090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:17
Query 'Please file in source.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:31:14
User opened query 'Please file in source.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 22:16:08
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	31 Dec 2020 16:20:56

US3792090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:17
User entered '31 Dec 2020'	Ann Marie Milliken (b) (4)	31 Dec 2020 16:20:56

US3792090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:17
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	31 Dec 2020 16:20:56

US3792090

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:17
User entered empty.	Ann Marie Milliken (b) (4)	31 Dec 2020 16:20:56

US3792090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:38
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	31 Dec 2020 16:21:02

US3792090

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:34:31
User entered '1'	System	31 Dec 2020 16:21:02

US3792090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:59:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	19 Feb 2021 19:14:26

US3792090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:59:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '1 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	19 Feb 2021 19:14:26

US3792090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:59:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	19 Feb 2021 19:14:26

US3792090

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:59:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	19 Feb 2021 19:14:26

US3792090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:59:44
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	19 Feb 2021 19:14:32

US3792090

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:19:22
User entered '1'	System	19 Feb 2021 19:14:32

US3792090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:01:21
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:52:18

US3792090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:01:21
User entered '5 Mar 2021'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:52:18

US3792090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:01:21
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:52:18

US3792090

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:01:21
User entered empty.	Ann Marie Milliken (b) (4)	05 Mar 2021 18:52:18

US3792090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User closed query 'Per GCL Lab Recon: Immuno: Per latest Preclarus report, there is an "Unscheduled[2]" Immuno 5 sample collected on "12 JAN 2021" with sample barcode# 1F652923590 and received to PPD GCL on 14 JAN 2021 with test result date released on 16 JAN 2021. Please kindly confirm if this "Unscheduled[2]" sample belongs to V4 D209 Immuno sample, if yes please kindly update the missing sample data here in EDC and also kindly send a DCF to update the correct visit label in PPD GCL records as well. Thank you. ' (Site from DM). Query 'Per GCL Lab Recon: Immuno: Per latest Preclarus report, there is an "Unscheduled[2]" Immuno 5 sample collected on "12 JAN 2021" with sample barcode# 1F652923590 and received to PPD GCL on 14 JAN 2021 with test result date released on 16 JAN 2021. Please kindly confirm if this "Unscheduled[2]" sample belongs to V4 D209 Immuno sample, if yes please kindly update the missing sample data here in EDC and also kindly send a DCF to update the correct visit label in PPD GCL records as well. Thank you. ' answered with 'Imunno 5 sample # 1F652923590 was collected as Day 28 convalescent visit. Unscheduled kit used. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:20:00
User opened query 'Per GCL Lab Recon: Immuno: Per latest Preclarus report, there is an "Unscheduled[2]" Immuno 5 sample collected on "12 JAN 2021" with sample barcode# 1F652923590 and received to PPD GCL on 14 JAN 2021 with test result date released on 16 JAN 2021. Please kindly confirm if this "Unscheduled[2]" sample belongs to V4 D209 Immuno sample, if yes please kindly update the missing sample data here in EDC and also kindly send a DCF to update the correct visit label in PPD GCL records as well. Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 17:16:40
DataPoint Verified.	Abram Burgher (b) (4)	06 Apr 2021 13:27:56
	(b) (4), (b) (6)	01 Apr 2021 21:01:39
	(b) (4), (b) (6)	24 Mar 2021 20:02:28

US3792090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:52:24

US3792090

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:42
User entered 'I'	System	05 Mar 2021 18:52:24

US3792090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:50:48

US3792090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered '5 Apr 2021'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:50:48

US3792090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:50:48

US3792090

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:50:48

US3792090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:50:53

US3792090

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 16:50:53

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:22
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User closed query 'Per ETRTR, Pleas complete Illness Visit for 14Dec20. Thanks!' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:03:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 and 18DEC2020 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)	20 Jan 2021 07:42:21
Query 'Per ETRTR, Pleas complete Illness Visit for 14Dec20. Thanks!' answered with 'illness visit entered ' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:59:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 and 18DEC2020 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 'illness visit now entered into EDC' (Site from DM).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:59:27
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 21:19:56
User opened query 'Per ETRTR, Pleas complete Illness Visit for 14Dec20. Thanks!' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 17:01:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 and 18DEC2020 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 05:07:03
User entered '14 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:07:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:22
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 and 22DEC2020 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)	20 Jan 2021 07:42:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 and 22DEC2020 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 'Saliva log updated ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:00:24
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 21:19:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 and 22DEC2020 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 09:49:25
User entered '11:00'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:07:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:22
User entered '14 Dec 2020 11:00'	System	17 Dec 2020 22:07:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:22
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:19:56
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:07:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:22
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:19:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:07:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 1 (Day 1)'	Scarlett Hammett (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:49
User entered '12 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:51
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:52
User entered missing code ND - Not Done.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:53
User entered missing code ND - Not Done.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:34
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:10
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:36
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:38
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:39
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:41
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:42
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:05
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:44
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:45
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:49
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:47
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:51
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:53
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:25:56
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:26
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:18:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 2 (Day 2)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:20:23
	(b) (4)	

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:27
User entered '13 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:29
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:31
User entered missing code ND - Not Done.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:33
User entered missing code ND - Not Done.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:29:38
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:29:40
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:35
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:37
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:29:45
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:03
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:21
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:01
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 21:29:55
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 21:29:53
User entered 'Moderate (Moderate)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:39
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:41
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:29:30
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:43
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:45
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:46
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:48
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:30:50
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:20:23

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 3 (Day 3)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:22:27
	(b) (4)	

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:24
User entered '14 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:23
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:21
User entered '99'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:19
User entered '98.5' F	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:32
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:29
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:30
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:28
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:38
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:42
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:44
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:47
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:52
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:54
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:32:59
User entered 'Mild (Mild)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:04
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:08
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:18
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:14
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:33:16
User entered 'None (None)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:22:27

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 4 (Day 4)'	(b) (4) Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:26
User entered '15 Dec 2020'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:39
User entered '0'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:32
User entered '99'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:35
User entered '98.5' F	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:48
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:47
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:41
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:52
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:35:57
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:00
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:02
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:05
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:10
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:12
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:18
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:24
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:36
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:34
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:36:27
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:32:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 5 (Day 5)'	(b) (4) Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:15
User entered '16 Dec 2020'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:12
User entered '0'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:34:37
User entered '99'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:07
User entered '98.7' F	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:16
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:18
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:19
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:23
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:27
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:29
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:41
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:39
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:37
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:46
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:02
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:58
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:55
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:37:52
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:07
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:34:38

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 6 (Day 6)'	(b) (4) Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:38
User entered '17 Dec 2020'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:40
User entered '0'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:41
User entered '99'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:47
User entered '98.6' F	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:53
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:54
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:03
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:04
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:38:56
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:12
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:13
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:49
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:15
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:17
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:28
User entered 'Moderate (Moderate)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:44
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:36
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:38
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:39:23
User entered 'None (None)'	Ann Marie Milliken (b) (4)	17 Dec 2020 22:36:39

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 7 (Day 7)'	(b) (4) Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:20
User entered '18 Dec 2020'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:19
User entered '0'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:16
User entered '99'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:17
User entered '98.9' F	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:28
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:26
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:29
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:31
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:37
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:38
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:25
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:21
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:40:57
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:31
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:48
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:38
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:42
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	18 Dec 2020 22:02:25

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 8 (Day 8)'	Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:28
User entered '19 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:26
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:24
User entered '98' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered '99'	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:23
User entered '98.5' F reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:38
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:42
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:43
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:51
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:53
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:54
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:42:56
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:43:11
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User closed query 'Per source, loss of smell is none, EDC states mild. Please reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 22:08:27
User signature succeeded.	(b) (4), (b) (6)	08 Apr 2021 22:07:35
Query 'Per source, loss of smell is none, EDC states mild. Please reconcile.' answered with 'updated' (Site from CRA).	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per source, loss of smell is none, EDC states mild. Please reconcile.' (Site from CRA).	Norma Frederick (b) (4)	13 Mar 2021 20:18:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	13 Mar 2021 20:18:26
	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 21:44:08
	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
	(b) (4)	
	Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58
	(b) (4)	

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:19
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:21
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:25
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:26
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:28
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:32
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:03:06
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 15:50:58

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 9 (Day 9)'	Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:58
User entered '20 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:56
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:52
User entered '97' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:35:30
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	21 Dec 2020 22:35:30
User entered empty.	System	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:44:54
User entered '98.5' F reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:35:30
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:38:53
User closed query 'kindly review source again, Chills is Mild. Please update.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:38:34
Query 'kindly review source again, Chills is Mild. Please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 06:14:03
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 06:13:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 06:13:45
User opened query 'kindly review source again, Chills is Mild. Please update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:10:58
User closed query 'Per source, Chills is mild, EDC states none. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:10:58
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Query 'Per source, Chills is mild, EDC states none. Please reconcile.' answered with 'Per source, chills is NONE correct as entered' (Site from CRA).	(b) (4) Norma Frederick (b) (4)	13 Mar 2021 20:19:15
User opened query 'Per source, Chills is mild, EDC states none. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 21:45:46
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:45:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:45:57
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:04
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:06
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:08
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:09
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:11
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:16
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:23
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:26
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:46:31
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:51:41
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:51:45
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:51:46
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:51:51
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 16:06:08
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 16:04:55

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 10 (Day 10)'	Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '21 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:11
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:07
User entered '98'	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:09
User entered '98.4' F	Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:20
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4) (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:28
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:30
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:34
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33
	(b) (4)	

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:45
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:47
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:51
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:50
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:54
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:55
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:57
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:52:58
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:00
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:01
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:03
User entered 'None (None)' reason for change: Data Entry Error	Bettie Corcoran (b) (4)	21 Dec 2020 22:37:28
User entered empty.	(b) (4) Bettie Corcoran (b) (4)	21 Dec 2020 22:36:33

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 11 (Day 11)'	Bettie Corcoran (b) (4)	22 Dec 2020 21:46:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:36
User entered '22 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:38
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:45
User entered '99'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:46
User entered '98.5' F	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:48
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:40
User entered 'Mild (Mild)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:49
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:50
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:52
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:53
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:55
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:56
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:58
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:53:59
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:01
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:02
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:04
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:05
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:07
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:09
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	22 Dec 2020 21:46:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 12 (Day 12)'	Bettie Corcoran (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:35
User entered '23 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:37
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:40
User entered '99'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:41
User entered '98.5' F	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:44
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:32
User entered 'Mild (Mild)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:11
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:09
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:08
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:06
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:04
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:02
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:01
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:58
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:56
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:52
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:54
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:50
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:49
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:54:47
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	23 Dec 2020 21:23:05

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 13 (Day 13)'	Bettie Corcoran (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:37
User entered '24 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:35
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:32
User entered '99'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:34
User entered '98.5' F	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:46
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:44
User entered 'Mild (Mild)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:48
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:49
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:51
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:52
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:55
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:55:56
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:01
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:00
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:03
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:04
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:06
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:08
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:09
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:56:11
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:22:35

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 14 (Day 14)'	Bettie Corcoran (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:45
User entered '25 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:47
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:49
User entered '99'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:50
User entered '99.0' F	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:52
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:44
User entered 'Mild (Mild)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:54
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:55
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:56
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:57
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:59:59
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:02
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:05
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:07
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:08
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:10
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:11
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:13
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:18
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:16
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:23:41

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User closed query 'Please enter Day 16, 17 and 18 in EDC.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:19:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Query 'Please enter Day 16, 17 and 18 in EDC.' answered with 'These are already entered ' (Site from CRA).	(b) (4) Norma Frederick (b) (4)	13 Mar 2021 20:20:43
User opened query 'Please enter Day 16, 17 and 18 in EDC.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 22:02:57
User entered 'Day 15 (Day 15)'	Bettie Corcoran (b) (4)	26 Dec 2020 23:24:52
	(b) (4)	

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:00:58
User entered '26 Dec 2020'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:00
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:02
User entered '99'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:04
User entered '99.0' F	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:05
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:07
User entered 'Mild (Mild)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:08
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:10
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:14
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:12
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:16
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:18
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:19
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:23
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:29
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:31
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:33
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:34
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:36
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:38
User entered 'None (None)'	Bettie Corcoran (b) (4) (b) (4)	26 Dec 2020 23:24:52

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 16 (Day 16)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:30:56
User entered '27 Dec 2020'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:30:58
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:02
User entered '99'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:22:11
User entered '97.9' F	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:22:09
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:22:07
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:22:04
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:22:01
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:21:59
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:21:57
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:21:55
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:21:53
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:20:06
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:48
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:46
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:45
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:43
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:38
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:37
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:15:57

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 17 (Day 17)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:03
User entered '28 Dec 2020'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:01
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:19:00
User entered '99'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:57
User entered '97.8' F	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:55
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:53
User entered 'Mild (Mild)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:49
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:47
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:45
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:44
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:42
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:39
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:37
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:35
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:33
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:30
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:28
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:26
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:18:44

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Day 18 (Day 18)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:04
User entered '29 Dec 2020'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:18:00
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:58
User entered '99'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User entered '%'	System	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:56
User entered '98.7' F	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:54
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:52
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:49
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:47
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:46
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:44
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:42
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:40
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:38
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:36
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:34
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:30
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:17
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:51:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:17:15
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 19:20:06

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 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 details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Apr 2021 06:28:16
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 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 details under appropriate visit or provide clarification, thank you.' answered with 'These samples have already been added under "Blood Sample Collection for Immunologic Assessment" page in Illness Visit folder.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:10:02
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:05:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 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 details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 05:01:21
User entered '14 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[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 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[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 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
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) (4), (b) (6)	25 Jan 2021 21:11:51
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE log has entry of covid -19' (Site from System).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:50:02
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:05:49
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	17 Dec 2020 22:23:43
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27DEC2020 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 05:55:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27DEC2020 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 '27Dec2020 Saliva sample is listed under saliva collection log - Day 14.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 20:44:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27DEC2020 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)	18 Jan 2021 06:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered '14 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[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 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:05:49
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:51:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:35
User entered '1'	System	17 Dec 2020 22:23:43

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

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 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:25:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:25:37
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:25:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:25:26
User entered empty; reason for change Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:25:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:24:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:24:20
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:24:04
User entered empty.	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:24:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:24:29
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 22:24:04
	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:28:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:28:02
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:28:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 22:24:04
	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:28:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:28:02
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:28:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 22:24:04
	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:28:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:28:02
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:28:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 22:24:04
	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
User closed query 'Per CDM: Please consider completing the Evidence of Shock and Evidence of Pneumonia sections of this form.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:44:04
Query 'Per CDM: Please consider completing the Evidence of Shock and Evidence of Pneumonia sections of this form.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:30:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:29:57
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:32
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User opened query 'Per CDM: Please consider completing the Evidence of Shock and Evidence of Pneumonia sections of this form.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:56:44
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:34
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:36
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

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Generated On: 10 Jun 2021 09:51:14

[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:37
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:39
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:41
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:43
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:45
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:46
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:48
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:49
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:51
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:30:19
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:09:04
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:09:05
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:09:07
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:46:15
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 22:09:08
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[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 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 22:24:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 22:24:20
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 22:24:04
	Scarlett Hammett (b) (4)	17 Dec 2020 22:24:04
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

US3792090

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:51:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:41
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:08:28
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:24:04

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:51:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:37:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:09:17
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:07:50

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 3 (Day 3)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '16 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 5 (Day 5)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '18 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 7 (Day 7)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '20 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 9 (Day 9)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 19:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:38
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '22 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 14 (Day 14)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 19:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:38
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '27 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 21 (Day 21)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 19:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:38
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User entered '03 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User accepted default value 'Day 28 (Day 28)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:48:54
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 19:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:40:38
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:40:38

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:19
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Saliva sample dated 12 Jan 2021 is for illness VD28, accession number 1f634143272 no tracking number documented ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 07:00:13
DataPoint Verified.	Norma Frederick (b) (4) (b) (4)	20 Apr 2021 18:19:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:48:54
User closed query 'Per GCL Lab Reconciliation: Saliva: Date of collection (10Jan2001) is before the Date of Informed consent (07Oct2020) . Please verify and update the sample collection date as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 05:40:05
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 05:17:11
	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 20:01:24

US3792090

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Date of collection (10Jan2001) is before the Date of Informed consent (07Oct2020) . Please verify and update the sample collection date as appropriate. Thank you.' answered with 'updated ' (Site from DM).	Norma Frederick (b) (4)	03 Feb 2021 20:01:12
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:01:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Date of collection (10Jan2001) is before the Date of Informed consent (07Oct2020) . Please verify and update the sample collection date as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:56:44
User entered '10 Jan 2001'	Norma Frederick (b) (4)	19 Jan 2021 19:40:38
	(b) (4)	

US3792090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:42
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:31:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '14 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:57:19
User entered '14 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[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 10:04:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:31:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:24
User entered 'SICKD1'	System	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Jan 2021 18:57:19
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Jan 2021 18:57:19
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Jan 2021 18:56:51
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
User entered '14 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4)	19 Jan 2021 18:55:24
	(b) (4)	

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '11:13' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
User entered '14 Dec 2020 11:13'	System	19 Jan 2021 18:56:51
User entered empty.	System	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '75' in reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24
DataPoint set to visible.	System	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '290.5' lb reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4)	19 Jan 2021 18:55:24
DataPoint set to visible.	(b) (4)	19 Jan 2021 18:54:10

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '98.5' F reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '86' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
User entered 'bpm'	System	19 Jan 2021 18:56:51
User entered empty.	System	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
User entered 'breaths/min'	System	19 Jan 2021 18:56:51
User entered empty.	System	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '117' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
User entered 'mmHg'	System	19 Jan 2021 18:56:51
User entered empty.	System	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:56:51
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 18:56:51
User entered '80' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:56:51
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 18:55:24
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29
User entered 'mmHg'	System	19 Jan 2021 18:56:51
User entered empty.	System	19 Jan 2021 18:55:24

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29

US3792090

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:29

US3792090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:57:45

US3792090

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '14 Dec 2020'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:57:45

US3792090

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:51:14

[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 10:04:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:21
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:57:59

US3792090

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:40:21
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '14 Dec 2020'	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:57:59

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:46
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12JAN2021, however this data is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject using the "Add Event" button and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 04:56:02
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12JAN2021, however this data is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject using the "Add Event" button and update as appropriate.' answered with 'DCF submitted to Preclarus' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:25:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:29
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 12JAN2021, however this data is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject using the "Add Event" button and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:18:34
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:46
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:43:29
User entered '12 Jan 2021'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[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 10:04:46
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:43:29
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:46
User entered 'SICKD28'	System	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '12 Jan 2021'	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '11:45'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
User entered '12 Jan 2021 11:45'	System	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered missing code ND - Not Done.	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 19:53:30
DataPoint set to visible.	(b) (4) System	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered missing code ND - Not Done.	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 19:53:30
DataPoint set to visible.	(b) (4) System	03 Feb 2021 19:51:23

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '97.9' F	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered empty.	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '68'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
User entered 'bpm'	System	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '16'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
User entered 'breaths/min'	System	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '120'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
User entered 'mmHg'	System	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:43:57
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '80'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51
User entered 'mmHg'	System	03 Feb 2021 19:53:30

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:51

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:45:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:54:58

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:04:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:45:11
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '12 Jan 2021'	(b) (4) Norma Frederick (b) (4)	03 Feb 2021 19:54:58

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:51:14

[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 10:05:00
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:45:14
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	03 Feb 2021 19:59:02

US3792090

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:51:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:05:00
User closed query 'Per GCL Lab Recon: SARS-COV2: Per SARS Preclarus report, there is no record of this SARS sample collected on "12 JAN 2021". Please kindly review and confirm if this sample is collected and if sample is collected and shipped to PPD GCL. Please kindly provide Accession # and received date to PPD GCL. Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Abram Burgher (b) (4)	20 Apr 2021 21:29:30 19 Apr 2021 16:13:55
Query 'Per GCL Lab Recon: SARS-COV2: Per SARS Preclarus report, there is no record of this SARS sample collected on "12 JAN 2021". Please kindly review and confirm if this sample is collected and if sample is collected and shipped to PPD GCL. Please kindly provide Accession # and received date to PPD GCL. Thank you. ' answered with 'DCF submitted to preclarus to change UV to CONV D28' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:29:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:45:14
User opened query 'Per GCL Lab Recon: SARS-COV2: Per SARS Preclarus report, there is no record of this SARS sample collected on "12 JAN 2021". Please kindly review and confirm if this sample is collected and if sample is collected and shipped to PPD GCL. Please kindly provide Accession # and received date to PPD GCL. Thank you. ' (Site from DM). User entered '12 Jan 2021'	(b) (4), (b) (6) Norma Frederick (b) (4)	17 Mar 2021 22:57:04 03 Feb 2021 19:59:02

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:20
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:31

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:20
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:31

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:20
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:31

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:37:31

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:27:50
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 15:56:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:26:11

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:44:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:27:50
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:09:24
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 15:57:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 15:56:42
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 06:09:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:26:11

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:53:30
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:53:30
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:09:55
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '1'	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:51:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '1'	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered empty.	System	19 Jan 2021 18:40:10
DataPoint set to visible.	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered empty.	System	19 Jan 2021 18:40:10
DataPoint set to visible.	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '10:27'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '19 Jan 2021 10:27'	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '98.2' F	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '66'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'bpm'	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '16'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'breaths/min'	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '111'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'mmHg'	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '75'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'mmHg'	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered empty.	System	19 Jan 2021 18:40:10
DataPoint set to visible.	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:42:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 19:42:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:42:57
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 18:40:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '19 Jan 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '12:22' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '19 Jan 2021 12:22'	System	19 Jan 2021 19:42:57
User entered empty.	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '98.5' F reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '60' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'bpm'	System	19 Jan 2021 19:42:57
User entered empty.	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:42:22
User closed query 'Per source, Resp. rate is 17, EDC states 16. please update' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:42:08
Query 'Per source, Resp. rate is 17, EDC states 16. please update' answered with 'edc updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 06:16:42
User entered '17' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 06:16:22
User opened query 'Per source, Resp. rate is 17, EDC states 16. please update' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:27:57
Query 'Per source, Resp. rate is 17, EDC states 16. please update' canceled (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:27:10
User opened query 'Per source, Resp. rate is 17, EDC states 16. please update' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 20:12:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:42:57
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'breaths/min'	System	19 Jan 2021 19:42:57
User entered empty.	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '128' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'mmHg'	System	19 Jan 2021 19:42:57
User entered empty.	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:12:12
User entered '80' reason for change: Data Entry Error	Norma Frederick (b) (4)	19 Jan 2021 19:42:57
User entered empty.	(b) (4) Norma Frederick (b) (4)	19 Jan 2021 18:40:10
	(b) (4)	

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'mmHg'	System	19 Jan 2021 19:42:57
User entered empty.	System	19 Jan 2021 18:40:10

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:06
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:39

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:39

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered empty.	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'mRNA-1273'	System	19 Jan 2021 19:41:28
DataPoint set to visible.	System	19 Jan 2021 18:37:50

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered '11:49'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '19 Jan 2021 11:49'	System	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:05
User entered 'ONCE'	System	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 19:41:28

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:27
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:06

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:27
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:06

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:27
User entered '10:32'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:06

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '19 Jan 2021 10:32'	System	19 Jan 2021 18:38:06

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:33
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:24

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:33
User entered '19 Jan 2021'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:24

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:33
User entered '10:37'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:24

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '19 Jan 2021 10:37'	System	19 Jan 2021 18:38:24

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:13:36
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:38:29

US3792090

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:26
User entered '1'	System	19 Jan 2021 18:38:29

US3792090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:16:20
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	26 Jan 2021 20:01:53

US3792090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:16:20
User entered '26 Jan 2021'	Ann Marie Milliken (b) (4)	26 Jan 2021 20:01:53

US3792090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:16:20
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	26 Jan 2021 20:01:53

US3792090

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:16:20
User entered empty.	Ann Marie Milliken (b) (4)	26 Jan 2021 20:01:53

US3792090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:16:28
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	26 Jan 2021 20:01:59

US3792090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User entered '1'	System	26 Jan 2021 20:01:59

US3792090

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:23
User entered '1'	System	26 Jan 2021 20:01:59
DataPoint set to visible.	System	26 Jan 2021 20:01:59

US3792090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:00
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:56:23

US3792090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:00
User entered '26 Feb 2021'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:56:23

US3792090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[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 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:00
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:56:23

US3792090

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'OLD29'	System	01 Mar 2021 05:56:23

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '26 Feb 2021'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '13:42'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered '26 Feb 2021 13:42'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '98.1' F	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '77'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'bpm'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '16'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'breaths/min'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '111'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'mmHg'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '77'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'mmHg'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '26 Feb 2021'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '14:29'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered '26 Feb 2021 14:29'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '98.5' F	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered empty.	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '75'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'bpm'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '16'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'breaths/min'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '104'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'mmHg'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 22:14:31
User closed query 'Per source, diastolic BP is 66, EDC states 75. Please update.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:14:19
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Query 'Per source, diastolic BP is 66, EDC states 75. Please update.' answered with 'EDC updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 22:10:52
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 22:10:32
User opened query 'Per source, diastolic BP is 66, EDC states 75. Please update.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 20:27:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 20:27:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:27:10
User entered '75'	Norma Frederick (b) (4)	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'mmHg'	System	01 Mar 2021 05:59:35

US3792090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:09
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:39

US3792090

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:09
User entered empty.	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 05:59:39

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

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 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'mRNA-1273'	System	01 Mar 2021 06:00:08
DataPoint set to visible.	System	26 Jan 2021 20:01:59

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered '26 Feb 2021'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered '13:55'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered '26 Feb 2021 13:55'	System	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:40
User entered 'ONCE'	System	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 06:00:08

US3792090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:43
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	01 Mar 2021 06:00:13

US3792090

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:38
User entered '1'	System	01 Mar 2021 06:00:13

US3792090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:28:37
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:54:35

US3792090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:28:37
User entered '5 Mar 2021'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:54:35

US3792090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:28:37
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	05 Mar 2021 18:54:35

US3792090

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:02:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:28:37
User entered empty.	Ann Marie Milliken (b) (4)	05 Mar 2021 18:54:35

US3792090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:00:52
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 18:54:41

US3792090

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:53
User entered '1'	System	05 Mar 2021 18:54:41

US3792090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:53:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:57:33

US3792090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:53:43
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '31 Mar 2021'	(b) (4) Norma Frederick (b) (4)	31 Mar 2021 19:57:33

US3792090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:53:43
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	31 Mar 2021 19:57:33

US3792090

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 19:57:33

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '31 Mar 2021'	Norma Frederick (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '12:11'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:11'	System	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '97.8' F	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered empty.	(b) (4) Norma Frederick (b) (4)	31 Mar 2021 19:58:06
	(b) (4)	

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '64'	Norma Frederick (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '16'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '111'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:54:33
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '75'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:58:06

US3792090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:53:54
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:59:15

US3792090

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:53:54
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered empty.	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:59:15

US3792090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:59:31

US3792090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '31 Mar 2021'	(b) (4) Norma Frederick (b) (4)	31 Mar 2021 19:59:31
	(b) (4)	

US3792090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:39
User entered '12:30'	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 19:59:31

US3792090

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:30'	System	31 Mar 2021 19:59:31

US3792090

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:51:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:13:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:01
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)'	(b) (4) Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:38:42

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:58:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:11
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:16
User entered 'USA-US057-2020-mRNA-1273-P301000004'	System	18 Dec 2020 20:28:44
User entered 'New'	(b) (4), (b) (6)	18 Dec 2020 20:28:44

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:58:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:53
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Dec 2020 22:42:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 22:42:54
Data point term sent to Coder	System	17 Dec 2020 22:42:07
User entered 'COVID 19'	Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:58:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '12 Dec 2020'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'No (N)' reason for change: New Information	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:12:06
User signature succeeded.	Abram Burgher (b) (4)	30 Apr 2021 15:01:31
User closed query 'PV Query: Please consider updating event end to the date symptoms resolved (per symptom log 29 Dec 2020)' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:23:03
Query 'PV Query: Please consider updating event end to the date symptoms resolved (per symptom log 29 Dec 2020)' answered with 'updated per symptom log 29 Dec 2020' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:24:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:24:11
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 20:24:11
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:24:11
User opened query 'PV Query: Please consider updating event end to the date symptoms resolved (per symptom log 29 Dec 2020)' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:43:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '28 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:05
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating event end to the date symptoms resolved (per symptom log 29 Dec 2020)' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:43:02
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:42:05
User opened query 'PV Query: Please consider updating event end to the date symptoms resolved (per symptom log 29 Dec 2020)' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:29:22
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:39:29
User entered empty.	System	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:26:40
User closed query 'Source states AE is serious, EDC stated not serious. Please update' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:26:24
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	09 Apr 2021 20:27:55
Query 'Source states AE is serious, EDC stated not serious. Please update' answered with 'updated ' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:19
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	09 Apr 2021 20:27:11
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:11
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:02
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User opened query 'Source states AE is serious, EDC stated not serious. Please update' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:05
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	17 Dec 2020 22:50:59
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	17 Dec 2020 22:45:37

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:45:37
User entered 'No (N)'	Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:26:57
DataPoint Un-verified.	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:55
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:55
User entered '1' reason for change: Per Query Resolution	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered '0' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:05
User entered '1' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:50:59
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '1'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
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)	20 Jan 2021 13:17:22
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)	19 Jan 2021 18:47:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:05
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 20:39:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:51
User closed query 'Source states recovered with sequelae, EDC does not indicate that. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:23:41
Query 'Source states recovered with sequelae, EDC does not indicate that. Please reconcile' answered with 'updated source' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 18:05:36
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User opened query 'Source states recovered with sequelae, EDC does not indicate that. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:34:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	17 Dec 2020 22:41:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Narrative](#)

Audit	User	Time (GMT)
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 condition". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:50:24
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 condition". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' answered with 'correct as entered: positive covid 19 is an SAE' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	19 Apr 2021 22:08:45
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 condition". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:28:54
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:35:34
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 13:17:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Jan 2021 13:17:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'CONMED LIST UPDATED ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:48:06
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 'EDC UPDATED ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	19 Jan 2021 18:47:43
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:38:47
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)	21 Dec 2020 20:38:17
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Dec 2020 22:50:59

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 22:50:59
User entered 'POSITIVE FOR COVID-19' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	17 Dec 2020 22:50:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Dec 2020 22:45:37
User entered empty.	Scarlett Hammett (b) (4)	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 20:27:11
User entered '0'	System	19 Jan 2021 18:47:05
User entered '1'	System	17 Dec 2020 22:45:37
User entered '0'	System	17 Dec 2020 22:41:27

US3792090

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:51:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:41:27

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:51:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:13:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:50:13
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:01:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:30:25
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	07 Oct 2020 21:57:40

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: VICKS NYQUIL COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 15:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 15:19:41
Data point term sent to Coder	System	06 Jan 2021 01:33:18
User entered 'NYQUIL - ACETAMINOPHEN 650MG, DEXTROMETHORPHAN 30MG, DOXYFAMINE SUCCINATE 12.5MG'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'COVID-19 SYMPTOM'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered '30'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'mL (mL)'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'as needed (PRN)'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered '13 Dec 2020'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:17
User closed query 'Per source, Stop date is recorded to be 23Dec, please update ' (Site from CRA). Query 'Per source, Stop date is recorded to be 23Dec, please update ' answered with 'edc updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:36:32
User entered 'No (N)' reason for change: Data Entry Error Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated edc' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 06:07:24
User opened query 'Per source, Stop date is recorded to be 23Dec, please update ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 06:07:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 06:07:01
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:51:18
	(b) (4), (b) (6)	09 Apr 2021 18:50:50
	(b) (4), (b) (6)	09 Apr 2021 18:50:46
	(b) (4), (b) (6)	26 Feb 2021 06:37:28
	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:36:19
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Apr 2021 06:07:11
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Apr 2021 06:06:43
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 06:06:43
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 06:06:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:50:46
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 01:32:42

US3792090

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:51:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:59:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:35
User entered 'No (N)'	Norma Frederick (b) (4)	05 Nov 2020 17:01:14

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'USA-US057-2020-MRNA-1273-P301000004'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Abram'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Burgher'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '3900 East Camelback Road'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Phoenix'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '85018'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'US'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 13:23:23
User entered '3'	System	12 Apr 2021 18:27:15
User entered '2'	System	20 Jan 2021 13:17:55
User entered '1'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'USA-US057-2020-MRNA-1273-P301000004'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Abram'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Burgher'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '3900 East Camelback Road'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Phoenix'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '85018'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'US'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 13:23:23
User entered '3'	System	12 Apr 2021 18:27:15
User entered '2'	System	20 Jan 2021 13:17:55
User entered '1'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:51:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '18/Dec/2020 15:28'	(b) (4) System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:51:14

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)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:29:05
User entered '1'	(b) (4), (b) (6)	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'USA-US057-2020-MRNA-1273-P301000004'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Abram'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Burgher'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '3900 East Camelback Road'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Phoenix'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '85018'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'US'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 13:23:23
User entered '3'	System	12 Apr 2021 18:27:15
User entered '2'	System	20 Jan 2021 13:17:55
User entered '1'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '20/Jan/2021 08:17'	(b) (4) System	20 Jan 2021 13:17:55

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:55

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'USA-US057-2020-MRNA-1273-P301000004'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Abram'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Burgher'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '3900 East Camelback Road'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Phoenix'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '85018'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'US'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 13:23:23
User entered '3'	System	12 Apr 2021 18:27:15
User entered '2'	System	20 Jan 2021 13:17:55
User entered '1'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
User entered '12/Apr/2021 14:27'	System	12 Apr 2021 18:27:15

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:23:12
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 18:27:15

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'USA-US057-2020-MRNA-1273-P301000004'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:13:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:35:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:26:58
Un-reviewed for Safety.	System	09 Apr 2021 20:27:55
DataPoint Un-verified.	System	09 Apr 2021 20:27:55
Signature has been broken.	System	09 Apr 2021 20:27:55
User entered 'Yes (Y)'	System	09 Apr 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'No (N)'	System	19 Jan 2021 18:47:05
User entered 'Yes (Y)'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Abram'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Burgher'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '3900 East Camelback Road'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'Phoenix'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered '85018'	System	18 Dec 2020 20:28:44

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:58:02
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:01:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:17:47
User entered 'US'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 13:23:23
User entered '3'	System	12 Apr 2021 18:27:15
User entered '2'	System	20 Jan 2021 13:17:55
User entered '1'	System	18 Dec 2020 20:29:00

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:12:14
User signature succeeded.	Abram Burgher (b) (4)	30 Apr 2021 15:01:31
User entered '30/Apr/2021 08:23'	(b) (4) System	30 Apr 2021 13:23:23

US3792090

Folder: SAE USA-US057-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:14

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)	01 May 2021 03:12:14
User signature succeeded.	Abram Burgher (b) (4)	30 Apr 2021 15:01:31
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:23:23